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CHEMICAL
RESEARCH,
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CENTER

CRDEC-CR-88085

LEAKAGE ASSESSMENT OF PROTECTIVE GAS MASKS

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August 1988

U.S. ARMY
ARMAMENT
MUNITIONS
CHEMICAL COMMAND

Aberdeen Proving Ground, Maryland 21010-5423

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UNCLASSIFIED
SECURITY CLASSIFICATION OF THIS PAGE

REPORT DOCUMENTATION PAGE

1a. REPORT SECURITY CLASSIFICATION UNCLASSIFIED	1b. RESTRICTIVE MARKINGS
2a. SECURITY CLASSIFICATION AUTHORITY	3. DISTRIBUTION/AVAILABILITY OF REPORT Approved for public release; distribution is unlimited
2b. DECLASSIFICATION/DOWNGRADING SCHEDULE	
4. PERFORMING ORGANIZATION REPORT NUMBER(S) CRDEC-CR-88085	5. MONITORING ORGANIZATION REPORT NUMBER(S)
6a. NAME OF PERFORMING ORGANIZATION Johns Hopkins University 6b. OFFICE SYMBOL (If applicable)	7a. NAME OF MONITORING ORGANIZATION U.S. Army Research Office
6c. ADDRESS (City, State, and ZIP Code) 615 North Wolfe Street Baltimore, MD 21205	7b. ADDRESS (City, State, and ZIP Code) P.O. Box 12211 Research Triangle, NC 27709-2211
8a. NAME OF FUNDING/SPONSORING ORGANIZATION CRDEC 8b. OFFICE SYMBOL (If applicable) SMCCR-PPI	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER DAAB-29-81-D-0100
8c. ADDRESS (City, State, and ZIP Code) Aberdeen Proving Ground, MD 21010-5423	10. SOURCE OF FUNDING NUMBERS PROGRAM ELEMENT NO. / PROJECT NO. / TASK NO. / WORK UNIT ACCESSION NO.

11. TITLE (Include Security Classification)

Leakage Assessment of Protective Gas Masks

12. PERSONAL AUTHOR(S)
Swift, David L., Ph.D.; Billings, Charles E., Ph.D.; and Shanty, Frank, Ph.D.

13a. TYPE OF REPORT	13b. TIME COVERED	14. DATE OF REPORT (Year, Month, Day)	15. PAGE COUNT
Contractor	FROM 82 Jul TO 83 Sep	1988 August	145

16. SUPPLEMENTARY NOTATION

COR: William Fritch, SMCCR-PPI, (301) 671-2519

17. COSATI CODES			18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number)
FIELD	GROUP	SUB-GROUP	Quantitative fit test, ~~(QNFT)~~
15	02		Aerosol test method
			Vapor test method

19. ABSTRACT (Continue on reverse if necessary and identify by block number)

This peer group review meeting of respiratory quantitative fit test (QNFT) methods was intended to consider (1) the advantages and disadvantages of presently used fit test methods, (2) the applicability of present methods to field effectiveness measurements, (3) improved methods for determining leakage of respirators, and (4) other research needs to put the field of respiratory protection on a firmer scientific footing.

Both instrumentation and methodology were considered in presentations, discussions and workshop sessions as important components of fit test measurement. An important concept enumerated early in the meeting was that fit tests serve several functions (such as research, evaluation, certification, point-of-issue, or field performance) and that specific appropriate methods should apply to each need. Thus, new fit test methods and instruments must be designed for determination of field effectiveness since present
(continued on reverse)

20. DISTRIBUTION/AVAILABILITY OF ABSTRACT	21. ABSTRACT SECURITY CLASSIFICATION
☒ UNCLASSIFIED/UNLIMITED ☐ SAME AS RPT. ☐ DTIC USERS	UNCLASSIFIED

22a. NAME OF RESPONSIBLE INDIVIDUAL	22b. TELEPHONE (Include Area Code)	22c. OFFICE SYMBOL
SANDRA J. JOHNSON	(301) 671-2914	SMCCR-SPS-T

DD FORM 1473, 84 MAR — 83 APR edition may be used until exhausted. All other editions are obsolete.

SECURITY CLASSIFICATION OF THIS PAGE
UNCLASSIFIED

19. ABSTRACT (Continued)

methods are only useable in the laboratory.

The development of respirator fit test methods from fiber filter penetration testing methodology involved several assumptions (such as maximum penetrating aerosol size) that are unproven for respirator leakage testing. There is a need to examine this issue as well as a need to improve the dilution and calibration methods for both oil and salt at low aerosol concentrations.

Fundamental studies of leakage as a function of particle size are needed, with special attention to ultra-fine particles (0.1 m). The use of aerosol particulates as a surrogate for vapor leakage needs to be critically examined and tested by simultaneous leakage measurements. Studies of the mixing of air within the cavity of full-face respirators are needed to elucidate the effect on leakage measurements and the role of design on rebreathing of mask cavity contents.

Once methods for field effectiveness measurements are developed, these should be applied to specific instances to obtain a data base for comparison of laboratory and field measurements. Initial studies suggest that present laboratory measurements may not be good predictors of field performance.

For point-of-use testing (non-intrusive tests) where integrity of the mask is maintained, development of accurate, inexpensive, and simple tests are needed. Several approaches appear to have potential for such measurements and should be investigated.

Both aerosol and vapor test methods for QNFT should be developed, as there are certain situations where vapor agents are more desirable than aerosols. Feasibility studies of non-intrusive vapor test methods should be supported as a possible field method.

Specific suggestions for needed research are included.

PREFACE

The work described in this report was authorized under Contract No. DAAB-29-81-D-0100. This work was started in July 1982 and completed in September 1983.

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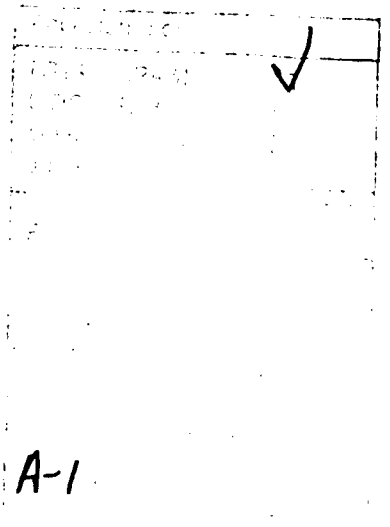

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1. INTRODUCTION

1.1 Purpose.

This report presents the results of a peer group review of the current state of quantitative measurement of the penetration of contaminants through or by the components of respiratory protective devices during use. A meeting was held March 24, 25, 1983 under the sponsorship of the U.S. Army as one task in a program to assess leakage of protective gas masks. Members of the peer review group are listed in Appendix A. The meeting agenda and schedule are given in Appendix B.

The purpose of this meeting on the review of respirator quantitative penetration test methods was:

- To identify and review current and potential future respirator quantitative fit test methods.
- To estimate the effectiveness of each current method in quantifying respirator leakage during field use.
- To identify advantages and disadvantages of each current method and to define studies necessary to overcome limitations.
- To develop a priority listing of potential new fit test methods for future investigation as an aid to R and D planning.

Although this review has been prepared under U.S. Army sponsorship, it is recognized at the outset that there are many user groups in the U.S. who have research and application responsibilities and allied interests in these matters. Many of these interested parties are included in the Peer Review Group. These interest groups include:

- Military; U.S. Army, U.S. Navy, U.S. Air Force
- Civilian Defense
- Nuclear Regulatory Commission and DOE/National Labs. (NuREG-0041 Respirator Manual)

- NIOSH/OSHA/MSHA
- ANSI; Z-88.2 programs, Z-88.6 medical
- Industrial Users
- (e.g., L.G. Birkner at Celanese; Steve Dixon and colleagues at du Pont Haskell Laboratories; K. Ostenstad at John Deere, etc.)
- Manufacturers of Devices (e.g., MSA, AO, Willson, 3M, etc.)
- Manufacturers of Devices (e.g., ATI, Baltimore; Dynatech Frontier, Albuquerque; TSI, Minneapolis)

1.2 Definitions.

1.2.1 Quantitative Fit Test (QNFT).

QNFT is a method including apparatus and procedures for the measurement of the concentration of an airborne test substance obtained from samples taken from inside a mask cavity or face piece (C_{int}), as compared to samples taken serially or simultaneously from the ambient space (chamber or hood) outside the mask cavity exterior, to the respiratory protective device (C_{ext}). The purpose of the test is to estimate the numerical fraction of material penetrating both the components of the respiratory protective device and the seal (or gasket) made between the device and the face, commonly called face fit. Penetration fraction is expressed as (C_{int}/C_{ext}). This is a laboratory test that may also be used at the point of issue of the device for the fitting of individuals, or in their training for donning, or use of devices for estimating maintenance effectiveness, etc. The QNFT provides an estimate of substance penetration. Time of testing is typically only a few minutes, with limited head movements.

1.2.2 Qualitative Fit Test (QLFT).

QLFT is a method including apparatus and procedures for detecting gross penetration or leakage by the use of an irritant, odorant,or other sensory stimulator. It is generally not possible to estimate the sensory stimulus inside the device in terms of a quantitative concentration.

1.2.3 Fit Factor (FF).

See Protection Factor.

1.2.4 Protection Factor (PF).

The PF is defined as C_{ext}/C_{int} determined from QNFT, a laboratory or point-of-issue (POI) determined value; also called Fit Factor.[1]

1.2.5 Factor for Maximum Use Concentration (FMUC).

The FMUC is equivalent to PF as defined above. Permitted Respirator Maximum Use Concentrations are obtained by multiplying the FMUC by the permissible exposure concentration appropriate to the specific substance from regulatory or practice guidelines.

1.2.6 Worker Use Factor (WUF).

WUF is a method for simultaneous measurement of the in-mask cavity (C_{int}) and exterior workplace (C_{ext}) concentrations of actual substances[2] for estimating respirator as-used breathing zone exposure. The test is conducted in the field using portable (personal) sampling pumps and appropriate collecting devices arranged to sample C_{int} and C_{ext} for the contaminant of interest. Typical operating test time would be several hours, such as a work shift, and the result may be expressed as penetration (C_{int}/C_{ext}) or WUF (1/Pen). This yields time-averaged leakage. Several other definitions expressing different test methods have been proposed by NIOSH.[2]

1.2.7 Effective Protection Factor.[2]

WUF corrected for non-wearing of respirato. during use.

1.2.8 Cold DOP (CDOP).

CDOP is polydisperse cold compressed air-generated dioctyl phthalate oil aerosol, PDOP (or DOS, DEHS, Corn Oil, etc. liquids).

1.2.9 Thermal DOP (HDOP).

HDOP or monodisperse is thermally-generated dioctyl phthalate oil aerosol, MDOP.

1.3 Overview of Respirator Effectiveness Tests.

It is assumed that readers are familiar with details of respirators and their use such as set out by Pritchard.[1] In reviewing the current state of the respiratory protective devices (respirators) testing, we have identified several significant factors in test objectives requiring consideration in the design and implementation of test methods (apparatus and procedures) as listed in Table 1.

Historically, certification for efficiency of removal of particulates, gases, and vapors by respirator air-purifying elements (filters, adsorbers, absorbers) has been performed in static chamber tests with simulant challenge substances (lead fume, silica dust, carbon tetrachloride) (Tables 2 and 3). Effectiveness of the assembled system was checked, using an irritant or odorous vapor or dark (coal) dust on test subjects at the certification lab. In 1960, in an attempt to develop respiratory protective devices for particulates significantly more toxic than lead, tests were performed on human subjects with a uranine test aerosol. These tests used as a basis the high efficiency all-glass fiber aerosol filter medium (99.97% removal efficiency on 0.3 μm DOP Smoke). An estimate of the average leakage was determined from a filter placed in the cavity and operated for 15-30 min, while subjects pedaled a bicycle. It was found from these tests that leakage was a significant factor in limiting the ability to achieve the high efficiency required for these devices. In the mid and late 60s, the techniques of man-testing for leakage were further developed by the British, using flame photometric determination of solid Sodium Chloride (NaCl) aerosol particles, and in the U.S. by LASL (Ed Hyatt, et al.) using light scatter from a DOP liquid particle aerosol. An estimate of instantaneous leakage was recorded for 5 min and an average was determined from leakage peak heights. These are laboratory tests that form the basis for a generic respirator leakage factor. These techniques have subsequently, in the 1970s, been adapted to quantitative fit tests, at the POI of the respirator prior to going to the work place (Table 4). In general, the DOP and NaCl test procedures do not yield the same leakage factor for a single individual tested.

Field test data at the point-of-use (POU) on concentrations of several different workplace substances determined simultaneously inside the mask and in the work environment during typical work activities, always yield leakage concentrations considerably greater than those determined by the quantitative face-fit test at the POI.

Type of Test	Purpose	Principal Test Method(s) Used	Respirator Element Tested
1. Research, Development, Testing or Evaluation, Laboratory Tests	To design or manufacture a better, more effective or less costly device; to solve a service problem or to develop a test method	A standard test method; or modified; or developed for the specific test purposes.	All components and assembly
2. Product Certification of Performance	To meet specifications or performance tests required for certification as manufactured.	Standard test methods	Both individual components and fully assembled devices
3. Point-Of-Issue (Fit) Test	To determine face fit effectiveness	Qualitative Fit Tests (QLFT) Quantitative Fit Tests (QNFT)	"Face-Fit" (all components)
4. Point-of Use Performance Test	To determine actual time-weighted average exposure to individual wearer.	Two collector-pump systems, one inside and one outside	"Face-Fit" (all components)
5. Recertification (Off-the shelf)	Quality assurance at point of sale, after shipment and storage.	Standard test methods	Both individual components and fully assembled devices
6. Shelf storage Availability	Quality assurance before issue, after sale and field storage	" " "	" " "
7. Reuse Effectiveness	To determine effectiveness of used devices after use and maintenance or repair	" " "	" " "

Table 1. Performance Tests for Respiratory Protective Devices.

Table 2. Development of U.S. Respirator Test Methods.

1. Test Schedules of the U.S. Bureau of Mines

Date	Item Certified	Schedule No.
1919	Self-Contained Breathing Apparatus (SCBA)	13
1919	Gas Masks	14
1927	Hose Masks	19
1934	Filter-Type Dust Fume, and Mist Respirators (F-T DFMR)	21
1944	Chemical Cartridge Organic Vapor Respirators (OVR)	23
1965	Modification of F-TDFMR, added the Uranine headform test	21B

2. NIOSH/MSHA; Schedules Consolidated, Extended, Recodified

1972 See Table 3 for quantitative fit-tests (QNFT) in these regulations 30 CFR 11.1 to 30 CFR 11.18 3.7

3. Development of Quantitative Fits Tests (Laboratory)

U.S. AEC Respirator Panel Recommendations 1958-59
Development of Uranine Test, HSPH, 1960
Adaptation of DOP Filter Test to respirators, LASL, 1960-65
Incorporate above two new tests into Bureau of Mines Schedule 21B, 1965
Development of modified NaCl test, HSPH - 1969-1970
In Recodificaton 2 above, NIOSH drops DOP fit and uranine headform tests, and adds DOP headform test, 1972

4. Quantitative Fit Tests Currently Used

DOP, DOS, Corn oil liquid particle aerosols
NaCl solid particle aerosols

5. Qualitative Fit Tests Currently Used

Pressure, suction, coal dust, isoamyl acetate (IAA), irritant smoke, saccharin

Table 2. Development of U.S. Respirator Test Methods (Continued).

6. Fit Test Methods Summary, 1982
QNFT Methods: Intrusive, objective data, elaborate and expensive equipment
QLFT Methods: Non-intrusive, subjective data, simple equipment

All of the above quantitative tests require a penetration through the mask facepiece to extract a sample of the internal mask cavity concentration. It would be beneficial if a test involving non-intrusive modifications could be developed. At the same time, there has been no development of generally recognized POI or POU tests for vapors. There is no reason to assume that leakage factors for vapors will be the same as determined by using aerosol tests.

There also appears to be several research questions raised by these issues, for example, what is the field-predictive value of a POI quantitative face fit? If, as it appears, the POI test is not a good predictor, how should actual field exposures be determined?

The non-intrusive test method would appear to offer a possibility to solve some of these issues. Types of non-intrusive methods that have been suggested include recovered samples (e.g., exhaled alveolar air concentration of a non-absorbed organic vapor), mask cavity real time detector or sampler, light-scattering device viewing interior of cavity for aerosol concentration, and color tape indicator.

These issues and QNFT experience have been reviewed at the peer group review meeting to provide a base for development of a set of mid- and long-range research recommendations for planning purposes.

2. ELEMENTS OF A RESPIRATOR FIT TEST SYSTEM - AND OVERVIEW OF METHODOLOGY.

Elements of a respirator fit test system and criteria, available choices, and factors influencing choices are presented in this section. The purpose is to lay out in logical order the

Table 3. Respirator Fit Test Requirements.

30 CFR 11 Subpart	Type of Facepiece	Test Atmosphere	Number of People Required for Test	Total Time of Test (min)	Exercises Required
H, Self-contained breathing apparatus (11.85-19)	Half mask, full facepiece, and mouthpiece	1000 ppm isoamyl acetate (IAA)	6	2	None required
I, Gas masks (11.102-3)	Half mask	100 ppm IAA	Not specified	8	Four 2-minute exercises specified
	Full face mask	1000 ppm IAA	Not specified	8	Four 2-minute exercises specified
J, Supplied-air respirators* (11.124-16 and -17, -18, -19, -20)	Half masks, full face masks, hoods, and helmets	1000 ppm IAA	Not specified	10	Two 5-minute exercises specified
	Respirators approved for sandblasting	—	Not specified	30	Sandblasting exercises specified
K, Dust, fume, and mist respirators	Half masks, full face masks, hoods, powered and nonpowered	For dusts and mists, no fit test required Fumes:			
TLV above 0.05 mg/m³		100 ppm IAA	Not specified	2	Not specified
	Single-use respirators for dust and mist	No fit test required			
TLV below 0.05 mg/m³	Half mask	100 ppm IAA	Not specified	5	2- and 3-minute exercises as specified
	Full face and hoods, powered and nonpowered, and mouthpieces	1000 ppm IAA	Not specified	5	Same as half mask, above
L, Chemical cartridge respirators	Half masks	100 ppm IAA	Not specified	8	Four 2-minute exercises specified
	Full face, hood, mouthpieces, powered and nonpowered	1000 ppm IAA	Not specified	8	Same as half mask, above
M, Pesticide respirators	Same as Subpart L, Chemical cartridge respirators				

*Tests must be made as follows: (1) 4 cfm for tight-fitting facepieces, 6 cfm for hoods and helmets, and (2) 15 cfm for both types.

*Silica dust is generated under conditions that duplicate sandblasting. Silica dust concentration is not specified, but dust generation procedur and subject activities are specified so the procedure can be duplicated. Maximum allowable SiO_2 dust within the hood = 0.32 mg/m³ (TLV for 1 percent SiO_2 = 0.29 mg/m³).

Table 4. Respirator Protection Factors.[1]

Type Respirator	Facepiece[2] Pressure	Protection Factor
I. Air-Purifying		
A. Particulate[3] removing		
Single-use,[4] dust[5]	–	5
Quarter-mask, dust[6]	–	5
Half-mask, dust[6]	–	10
Half- or Quarter-mask, fume[7]	–	10
Half- or Quarter-mask, High-Efficiency[8]	–	10
Full Facepiece, High-Efficiency	–	50
Powered, High-Efficiency, all enclosures	+	1000
Powered, dust or fume, all enclosures	+	X[9]
B. Gas and Vapor-Removing[10]		
Half-Mask	–	10
Full Facepiece	–	50
II. Atmosphere-Supplying		
A. Supplied-Air		
Demand, Half-mask	–	10
Demand, Full Facepiece	–	50
Hose Mask Without Blower, Full Facepiece	–	50
Pressure-Demand, Half-Mask[11]	+	1000
Pressure-Demand, Full Facepiece[12]	+	2000
Hose Mask With Blower, Full Facepiece	–	50
Continuous Flow, Half-Mask[11]	+	1000
Continuous Flow, Full Facepiece[12]	+	2000
Continuous Flow, Hood, Helmet, or Suit[13]	+	2000
B. Self-Contained Breathing Apparatus (SCBA)		
Open-Circuit, Demand, Full Facepiece	–	50
Open-Circuit, Pressure-demand Full Facepiece	+	10,000[14]
Closed-Circuit, Oxygen Tank-type, Full Facepiece	–	50
III. Combination Respirator		
A. Any combination of air-purifying and atmosphere-supplying respirator.	Use minimum protection factor listed above for type of mode of operation.	
B. Any combination of supplied-air respirator and an SCBA		

Exception: Combination supplied-air respirators, in pressure-demand or other positive pressure mode with an auxiliary self-contained air supply, and a full facepiece, should use the PF for pressure-demand SCBA.

[1] The overall protection afforded by a given respirator design (and mode of operation) may be defined in terms of its protection factor (PF). The PF is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of contaminant in the ambient atmosphere to that inside the enclosure (usually inside the facepiece) under conditions of use. Respirators should be selected so that the concentration inhaled by the wearer will not exceed the appropriate limit. The recommended respirator PF's are selection and use guides, and should only be used when the employer has established a minimal acceptable respirator program as defined in Section 3 of the ANSI Z88.2-1969 Standard.

Table 4. Respirator Protection Factors (Continued).[1]

[2] In addition to facepieces, this includes any type of enclosure or covering of the wearer's breathing zone, such as supplied-air hoods helmets, or suits.

[3] Includes dusts, mists, and fumes only. Does not apply when gases or vapors are absorbed on particulates and may be volatilized or for particulates volatile at room temperature. Example: Coke oven emissions.

[4] Any single-use dust respirator (with or without valve) not specifically tested against a specified contaminant.

[5] Single-use dust respirators have been tested against asbestos and cotton dust and could be assigned a PF of 10 for these particulates.

[6] Dust filter refers to a dust respirator approved by the silica dust test, and includes all types of media, that is, both nondegradable mechanical type media and degradable resin-impregnated wool felt or combination wool-synthetic felt media.

[7] Fume filter refers to a fume respirator approved by the lead fume test. All types of media are included.

[8] High-efficiency filter refers to a high-efficiency particulate respirator. The filter must be at least 99.97% efficient against 0.3 μm DOP to be approved.

[9] To be assigned, based on dust or fume filter efficiency for specific contaminant.

[10] For gases and vapors, a PF should only be assigned when published test data indicate the cartridge or canister has adequate sorbent efficiency and service life for a specific gas or vapor. In addition, the PF should not be applied in gas or vapor concentrations that are 1) immediately dangerous to life, 2) above the lower explosive limit, and 3) cause eye irritation when using a half-mask.

[11] A positive pressure supplied-air respirator equipped with a half-mask facepiece may not be as stable on the face as a full facepiece. Therefore, the PF recommended is half that for a similar device equipped with a full facepiece.

[12] A positive pressure supplied-air respirator equipped with a full facepiece provides eye protection but is not approved for use in atmospheres immediately dangerous to life. It is recognized that the facepiece leakage, when a positive pressure is maintained, should be the same as an SCBA operated in the positive pressure mode. However, to emphasize that it basically is not for emergency use, the PF is limited to 2,000.

[13] The design of the supplied-air hood, suit, or helmet (with a minimum of 6 cfm of air) may determine its overall efficiency and protection. For example, when working with the arms over the head, some hoods draw the contaminant into the hood breathing zone. This may be overcome by wearing a short hood under a coat or overalls. Other limitations specified by the approval agency must be considered before using in certain types of atmospheres.

[14] The SCBA operated in the positive pressure mode has been tested on a selected 31-man panel and the facepiece leakage recorded as less than 0.01% penetration. Therefore, a PF of 10,000+ is recommended. At this time, the lower limit of detection 0.01% does not warrant listing a higher number. A positive pressure SCBA for an unknown concentration is recommended. This is consistent with the 10,000+ that is listed. It is essential to have an emergency device for use in unknown concentrations. A combination supplied-air respirator in pressure-demand or other positive pressure mode, with auxiliary self-contained air supply is also recommended for use in unknown concentrations of contaminants immediately dangerous to life. Other limitations, such as skin absorption of HCN or tritium, must be considered.

elements and factors so that present or proposed methods can be measured against a set of suitability conditions.

Table 5 is a list of nine basic elements that were considered, starting with the test-substance. Every fit test system and methodology of testing must include these elements. Major systems and methods used to date will be discussed below, but a new fit test methodology could be assembled by choosing appropriate elements best fitted to a specific task. As detailed below, it may be desirable to use a specific apparatus and method for a particular type of fit test, such as a field test.

Table 5. Respirator QNFT - Apparatus and Procedure.

Basic Elements
Test Substance (aerosol, gas, vapor)
Generator
Air Supply, Handling, Mixing, Delivery
Exposure Volume - Chamber
Subject - Protocol
Respirator
Sampling System - Cavity
Sampling System - Chamber
Analysis - Measuring Concentration
Data Handling

Table 6 is a consideration of test substances for quantitative fit tests, including both gaseous and particulate matter. The criteria of choice are not prioritized. Both NaCl and oil (DOS, DOP, Corn oil, or PEG) meet the criteria for choice at the top of Table 6, but of the special aerosol criteria listed below, oil aerosol is more suitable because of the hygroscopic property of NaCl.

Viable aerosol does not enjoy wide use because of the difficulty of preparation and the method of collection. At the time it was first developed, it was assumed that only such a method could enable quantification of very low aerosol concentration. It now appears that light scattering or flame photometry have adequate sensitivity to detect concentrations low enough to obtain fit factors $\geq$ 10,000.

Several gases and vapors have been used to measure mask leakage. It is not known experimentally whether such substances

behave similarly to aerosols, with respect to gas mask leakage; but in principle the transport of a dilute vapor is different from an aerosol. Some of the gases used are easily adsorbed by the mask charcoal and can be used as leakage test agents. Other gases easily penetrate charcoal and must be excluded from the inhalation valve region by providing a separate source of vapor free air for inhalation. The influence of such "plumbing" on the performance of a respirator is not known, but is possible that such a mechanical connection can alter the face fit of the respirator. The gases or vapors must be nontoxic at the exposure concentration and a method of real time analysis that does not require large gas volume samples must be available.

Table 6. Test Substances.

Function - Indicate Leakage by Transport

Criteria For Choice

Non-Toxic
Chemically Stable, Non-Reactive
Available, Inexpensive
Detectable
Removable by Respirator Filters
Appropriate Leak Surrogate

Available Choices

Viable Aerosol - B. Globigii
Non-Viable Aerosol - Oil, Salt, Uranine, Other
Vapor - Chlorofluoromethane, Etc.
Gas - Helium, Argon, Ethylene, Sulfur Hexafluoride
Penthrane, Amylacetate, Methane

Special Aerosol Criteria

Rel. Monodisperse
Minimum Transport, Diff., Sed., Inertia
Non-Hygroscopic
Uncharged
Low Vapor Pressure

In addition to the above criteria, aerosols must meet additional criteria listed in Table 6. If the aerosol is significantly polydisperse ($\mu g \geq 1.5$), the selective leakage

(dependent on particle diameter) will generally lead to different size distributions on the exterior and interior of the respirator. Generally, this situation will cast doubt upon the measured "concentration" ratio for any presently used method of measurement. The appropriate size of aerosol particles to achieve minimum combined transport by sedimentation, inertia, and diffusion is not known for respirator leakage, since we do not know either the exact process or the geometry of the leakage path.

If the aerosol is hygroscopic (such as NaCl), it will undergo water vapor accretion and growth at high relative humidity (within mask and in respiratory tract). This factor will change its transport properties. Also, if the aerosol particles are composed of a liquid of significant vapor pressure, the particles will evaporate. The role of particle electric charge in respirator leakage is unknown, but it can be theorized that if particles are significantly charged (>100 charges/ particle) their collection at leakage surfaces will be altered.

Table 7 is a concise listing of generator characteristics for aerosol or vapor generating devices. The generator must have a sufficient output to reach a steady concentration about the subject's head in a short time ($\leq$10 min). It must have a constant output to maintain a constant concentration, but it is additionally desirable that the output be adjustable to provide for a range of conditions for detection. The additional criteria of operational simplicity, maintenance, and cost are desirable and for field use the criterion of portability is essential.

A representative list of choices is also shown in Table 7, and it is by no means exhaustive. The most widely used generators presently are the Laskin nebulizer (cold oil) and the Dautrebande nebulizer (NaCl solution). For gas mixtures, gas from a tank of known concentration is dispersed through a rotameter and mixed with air, also metered. Vapor mixtures are usually produced by nebulization of the corresponding liquid and mixture with clean, dry air. It is important for the gas or aerosol generator to be matched with the exposure chamber (see below).

Table 8 is a list of criteria and methods of air supply, mixing, and delivery. This subsystem should be designed to minimize agent loss, reaction, adsorption, and concentration variability. Volume should be small enough to permit rapid achievement of steady state in the chamber. If any air moving

elements are located between the generator and the chamber, they should not remove aerosol particles selectively with respect to size.

Table 7. Generator for Agents.

Function - Produce Agent-Air Mixture

Criteria for Choice

Constant, Measureable Output
Adjustable Output
Simple to Operate
Low Maintenance
Inexpensive
Portable

Available Choices

Laskin Nebulizer (Oil)
Dautreband Gen. (Salt, Sol'n)
Vaporization/Condensation (Salt Stick)
Ultrasonic Nebulizer (Sol'n)
Medical Jet Nebulizer (Uranine)
Spray Nozzle - B. Globigii
Nebulizers - Vapor
Metered Gas or Mixtures from Tank

Aerosol dilution without turbulent wall loss should be achieved in the delivery system. Several methods to supply air and mix aerosol with clean air are listed in Table 8. Prefiltration and removal of residual vapors are necessary for the supply air prior to mixing with aerosol or vapor streams.

Table 9 is concerned with the exposure chamber for leakage assessment. This important element of the system must provide for a constant aerosol or vapor concentration about the respirator and permit any required degree of activity. It must be enclosed with a non-reactive surface material and be easily accessible if the subject(s) must move in and out of the chamber.

In general, exposure chambers can range from a head hood upward in size to a multisubject room. It is desirable to have at least one visible wall so that the subject(s) can be observed from outside. If designed for field application, it

should be portable and durable. In one proposed approach to the respirator QNLT, no chamber is used; the natural nuclei of the atmosphere are considered the test aerosol to be measured both inside and outside the respirator.[4]

Table 8. Air Supply, Handling, Mixing, and Delivery.

Function - Carry Air-Agent Mixture to Chamber

Criteria for Choice

Low Volume
Constant Flow Rate of Air
Low Loss of Agent (Deposition, Adsorption)
Adequate Mixing
Leaktight
Nonreactive to Vapor, Gas
Nonpermeable

Choices

Air	Regulated Tank Air Vane Pump House Air (with Filter, Reg., and Drying)
Mixing	- Venturi, Turbulence
Delivery	- Stainless, Teflon

Factors associated with the subject that influence the system design and methodology are listed in Table 10. While some of the factors, such as anthropometric features, have been well addressed, others have received little attention, such as the variable uptake of the agent in the respiratory tract dependent on aerosol size or vapor absorption. The protocol for leak test is not based on the wide range of head and body movements possible while wearing a respirator but has been standardized for simplicity in several laboratories.

Table 11 lists several factors associated with the respirator itself that affect the measured leak factor, including mask space convection and leak location. While much attention has been given to the operation of the filters, charcoal, and valves, there are other factors that are undoubtedly just as important with respect to measurement protocol. Protocols for leakage measurement usually include head and jaw movement to simulate normal movements during respirator use.

Table 9. Exposure Volume in Chamber.

Function - Provide Constant Concentration Atmosphere in an Enclosed Volume for Test

Criteria for Choice

Well-Mixed
Large Enough for Subject(s) and Protocol
Leaktight
Easy Access
Observable for Test Protocol
Rapid Turnover of Agent
Portable, If Necessary
Durable

Available Choices

Head Hood
Upper Body Enclosure
Shower Stall, Modified
Fiber Glass Chamber, Vestibule
Custom Multisubject Chamber

Systematic studies of the effect of gravity and body position have not been performed. Acceleration which may affect peripheral seal and valve operation have likewise not been investigated.

All existing systems for measuring mask leakage employ a cavity sampling system whose features are outlined in Table 12. It is necessary with such systems to pierce the mask and to draw a certain flow of air out of the mask cavity. This flow must be made up by incoming flow either through the inspiratory valve or through leaks. The effect of the flow is not known, but it is considered desirable to minimize the flow rate. The system itself should have low volume and should not result in significant agent loss to the detection device.

A parallel system for determining the chamber concentration of the agent is also included in Table 12. Similar criteria are applied, except that it is not as crucial to have a low flow rate. If the same instrument is used to measure cavity and chamber agent concentration, a switching system can be used

alternately sampling both spaces. The point of sampling should be near the mask, representative of the agent entering the mask by the filter or by leakage processes.

Table 10. Subject Factors.

Factors Influencing In-Mask Concentration
Breathing Condition (Rate, Volume)
Mode (Mouth vs. Nose)
Respiratory Uptake of Agents
State of Exercise
Anthropometric Features
Facial Movements
Skin Uptake
Choice of Protocol for Leak-Test
Still
Standard Movements
Representative of Special Movements

Table 11. Respirator.

Function - Barrier to ATM. Contaminants by Seal, Filter Elements, and Valves.
Factor Affecting "In-Mask" Concentration
Convection in Cavity
Leak Location
Gravity Factors, Body Position
Accelerations

Table 13 concerns the analysis of agent that is delivered to an analyzer from the mask or chamber via the delivery system. Criteria listed are common to many instruments used for environmental agent detection; it is particularly important that the instrument have good accuracy at the low agent concentrations in the mask or chamber and that it be properly

calibrated. Eight different analytical approaches are listed as possible choices, but this list is not intended to be exhaustive.

Table 12. Cavity Sampling System.

Function - Extract Sample From Cavity for Concentration Det'n

Criteria

Low Volume
Low Flow Rate
Minimal Damage to Resp.
Representative of Breathed Air
Minimal Loss of Agent

Chamber Sample System

Function - As Above for Chamber

Criteria

Low Volume
Low Flow Rate
Short Response
Sample Near Mask

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3. LIQUID AEROSOL METHOD

Mr. Harry J. Ettinger of Los Alamos National Laboratory presented a summary of the use of oil aerosol to determine respirator leakage. Visual aids used during the talk are presented in Appendix C. The oil aerosol is generated from bulk liquid by a submerged compressed air-driven ejector nozzle (Laskin nozzle), usually with a baffle to remove large particles.[1] This produces a chamber concentration in the range of 1 to 4 mg/m^3. Aerosol particle size is log-normally distributed with a count median diameter of 0.4 μm and a geometric standard deviation of 1.5-2.0. This is equivalent to a mass median diameter of 0.9 μm (Figure 1).

The subject wears a respirator having a bulkhead fitting in the vicinity of the nose for in-cavity sampling. Aerosol samples at 1.5 Lpm are taken from the chamber and from the cavity through small diameter tubing to a forward light scattering photometer that is intended to give a continuous

indication of aerosol concentration. The dynamic range of the photometer was stated to be from 100% (at 4 mg/m^3) to 10^{-4} penetration or 4 x 10^{-4} mg/m^3. Cost of a commercial system was estimated to be in the range of $10,000 depending upon options, chamber configuration and systems for data acquisition, storage, processing, and presentation. A microprocessor controlled system to provide automatic functioning of total test with no need for a test operator was estimated to be as much as $100,000.

Table 13. Analyzer for Agent Concentration.

Function - Measure Cavity and Chamber Concentrations

Criteria

Sensitivity
Response
Accuracy
Selectivity
Precision
Wide Range
Existing Method of Calibration

Choices

Light Scattering Photometer
Flame Photometer
IR Spectrophotometer
Gas Chromatograph
Spectrophotometer
Halide Meter
Mass Spectrometer
CNC

Eleven different oils have been used for the generator (Appendix C) in order to respond to concerns for possible health effects with inhalation of DOP. No major particle size differences were observed. Problems with vegetable oils were observed, and these included odor and bacterial growth.

Advantages to the use of oil aerosol for respirator fit testing include those listed in Appendix C. It is the most widely used method in the U.S. and is based on the procedure for in-place filter testing of high-efficiency space filters.

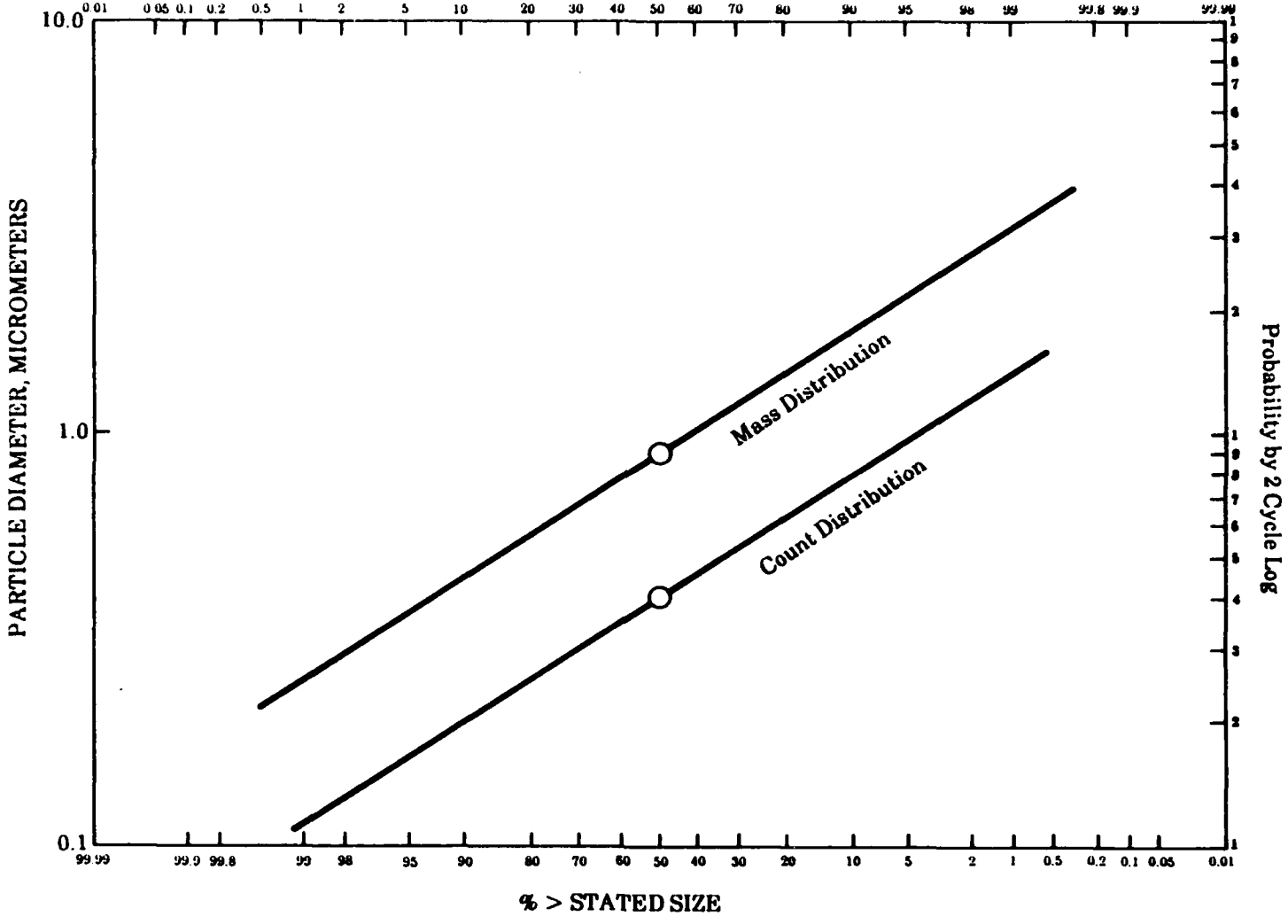


Figure 1. DOP Aerosol Size Distribution Reported by Ettinger (1983).

Furthermore, the systems are rugged, the aerosol is relatively reproducible in most user locations, several oils may be used, the size spectrum is in the respirable range, and aerosol deposition in the filter does not yield a measurable particle accumulation effect (commonly called loading with solid particle aerosols). The test is simple and quantitative, measuring leakage down to 10^{-4}. The data generated by LANL have been used to prepare Protection Factors for NIOSH (Table 4) as used by OSHA, and by MSHA for the determination of maximum use concentrations (Table 14).

Mr. Ettinger discussed the possible use of an active cavity laser configured to measure individual particles and size spectra within the mask cavity, and stated that it might be used at concentrations as low as 10^{-6} mg/m^3. Major limitations and current uncertainties associated with the use of oil aerosol particles were described. These include the possible toxicity of DOP (or other alternatives) and the question of oil product consistency when purchased at the local grocery store. The question of calibration of photometer output reading by measurement of actual mass concentrations at lower values was alluded to by Mr. Ettinger. The general method for calibrating the photometer is electronic only. This is analogous to the salt solution dilution method used to calibrate the NaCl system output. Neither system has been calibrated at low concentration by independently measuring the concentration corresponding to a given scattered light signal.

Another complexity enters from consideration of the particle size changes that occur as particles penetrate various orifices, slots, filter materials, gaskets, or valves of the respirator. Also, there is a limitation for measuring lower concentrations that are currently performed. Although measurements of lower concentrations are technically feasible by light scattered from spherical particles with real refractive indexes, more work is needed to improve the system. Mr. Ettinger felt that non-intrusive measurements of penetration using oil aerosols was a fruitful field for further work.

Mr. Ettinger discussed limitations and uncertainties in the areas of general test methodology (i.e., apparatus and procedures for its use). He felt there should be attempts to standardize the test methodology, including the sampling flow rates and penetration producing exercises. There appears to be a need to set up criteria for a specified size distribution that all generating devices should produce, and a specific method for its periodic measurement at each test location. Mr. Ettinger

Table 14. Respirator Maximum Use Concentrations.[a]

	Permitted for Use in Oxygen-Deficient Atmosphere	Permitted for Use in Immediately-Dangerous-to-Life-or-Health Atmosphere	Factor for Maximum-Use Concentration
AIR-PURIFYING RESPIRATORS			
Particulate filter, quarter-mask facepiece[bc]	No	No	5
Particulate filter, half-mask facepiece[bc]			
With disposable mask	No	No	5
With replaceable filters	No	No	10
Particulate filter, full-mask facepiece[b]			
With dust, fume, mist filter	No	No	10
With high-efficiency filter	No	No	50
Powered, air-purifying[bc]			
With dust, fume, mist filter	No	No	100
With high-efficiency filter	No	No	1000
Vapor- or gas-removing[ef], quarter- or half-mask facepiece[e]	No	No	10
Vapor- or gas-removing[ef], full-mask facepiece	No	No	50
SUPPLIED-AIR RESPIRATORS			
Hose mask, with or without blower, full-mask facepiece	Yes	No	10
Air-line demand, quarter- or half-mask facepiece, with or without escape provisions[cd]	Yes	No	10
Air-line demand, full-mask facepiece, with or without escape provisions[d]	Yes	No	50
Air-line pressure-demand or continuous flow,			
Quarter- or half-mask facepiece			
Without escape provisions[c]	Yes	No	1000
With escape provisions[cd]	Yes	Yes	1000
Full-mask facepiece, helmet, hood, or suit			
Without escape provisions	Yes	No	2000
With escape provisions	Yes	Yes	2000
SELF-CONTAINED BREATHING APPARATUS			
Demand-type open-circuit or negative-pressure-type closed circuit			
Quarter- or half-mask facepiece[c]	Yes	No	10
Full-mask facepiece or mouthpiece/nose clamp[c]	Yes	No	50
Pressure-demand-type open-circuit or positive-pressure-type closed-circuit[c]	Yes	Yes	10,000+[g]
COMBINATION RESPIRATORS	The type and mode of operation having the lowest factor for maximum-use concentration shall be applied to the combination.		

[a] Respirator maximum-use concentrations are determined by multiplying the factor given in Table 5-2 by the PEL.

[b] When the respirator is used for protection against airborne particulate matter having a PEL less than 0.05 mg/m^3, or for protection against airborne radionuclide particulate matter, the respirator shall be equipped with a high efficiency filter(s).

[c] If the airborne substance causes eye irritation, the wearer of a respirator equipped with a quarter-mask or half-mask facepiece or a mouthpiece/nose clamp shall be permitted to use a protective goggle or to use a respirator equipped with a full-mask facepiece.

[d] The escape provision shall be an auxiliary self-contained supply of respirable air.

[e] The service life of a vapor- or gas-removing cartridge or canister depends on the specific vapor or gas, the concentration of the vapor or gas in air, the temperature and humidity of the air, the type and quantity of the sorbent in the cartridge or canister, and the activity of the respirator wearer. Cartridges and canisters may provide only short service lives for certain vapors and gases. Vapor/gas service life testing is recommended to ensure that cartridges and canisters provide adequate service lives.

[f] Vapor- and gas-removing respirators are not approved for substances that lack adequate warning properties of taste, odor, or irritation at concentrations in air at or above the PEL.

[g] The respirator has been classified for use in atmospheres having unknown concentrations of airborne substances.

* From MSHA, proposed; July 1983.

described the two methods of interpreting the instantaneous in-mask concentration record from a strip chart: computing the mean value of the peaks of concentration[5] or integrating the total area under the concentration curve to obtain an average concentration. Changing from average of penetration peaks,[1,5] to the integrated area average, does not appear to yield comparable results. The integrated area method yields a lower penetration, and represents a systematic difference in reporting of unknown and variable amount.

In terms of particle size distribution and concentration, the actual interpretation of the instrument output signal continues to be an unresolved issue. The test as conducted measures "light-scatter" fit factor from light scatter concentration estimates, on what may be two different aerosol particle populations. Neither mass nor number concentration are directly measured. Although not referred to here specifically, an unknown amount of aerosol lung deposition (size-dependent) during inhalation and exhalation also affects the measured in-mask concentration.

It is also important to determine what effect aerosol inlet dimension, configuration, and location has on size selective sampling efficiency. The assumption now used is that one is measuring an appropriate breathing zone concentration by locating the inlet in the vicinity of the nose.

The lack of agreement that now exists in the technical community with respect to terminology and definitions for tests and results was discussed.[2,6] Mr. Ettinger indicated a need for standard definitions of terms to go along with the standard methods proposed above. The whole question of test interpretation in terms of probability of exposure of a worker to a toxic agent above an allowed value was discussed. Each measurement is a member of a population of results that shows an unknown degree of intra- and inter-subject variability. The quantitative treatment of this phenomenon for prediction was felt to need further study.

Mr. Ettinger expressed a concern for overly refined test methodology when the overriding concern in general worker populations (excluding military ordnance and radioactive dose hazards) is whether the workers wear the respirator and for how long, during exposure. A tabulation of the reduction in worker protection factor (or increase in average penetration or exposure concentration) was provided as shown in Table 15. Professor F.

Rosenthal, of our staff prepared a similar presentation for use in training of workers in an asbestos control program (Figure 2).

Questions regarding the type of exercises or head or body motions to be included in respirator fit test protocols continue to be of concern in dose estimations caused by respirator leakage. Some LANL/MSHA studies with SCBA on human performance, and USAF treadmill exercise results were mentioned, primarily from the cardiovascular standpoint.

Table 15. Effect of Off Time on Effective PF.

	Time Not Worn (Fraction)				
FF	0.8	0.5	0.2	0.1	0
10	1.2	1.8	3.6	5.2	10
100	1.2	2.0	4.8	9.2	100
1000	1.3	2.0	5.0	10.0	1000

N.B., Data derived from (Revoir):

$$WUF = \frac{FF}{(F\ F)\left(\frac{\text{Time not Worn}}{\text{Time Worn}}\right)}$$

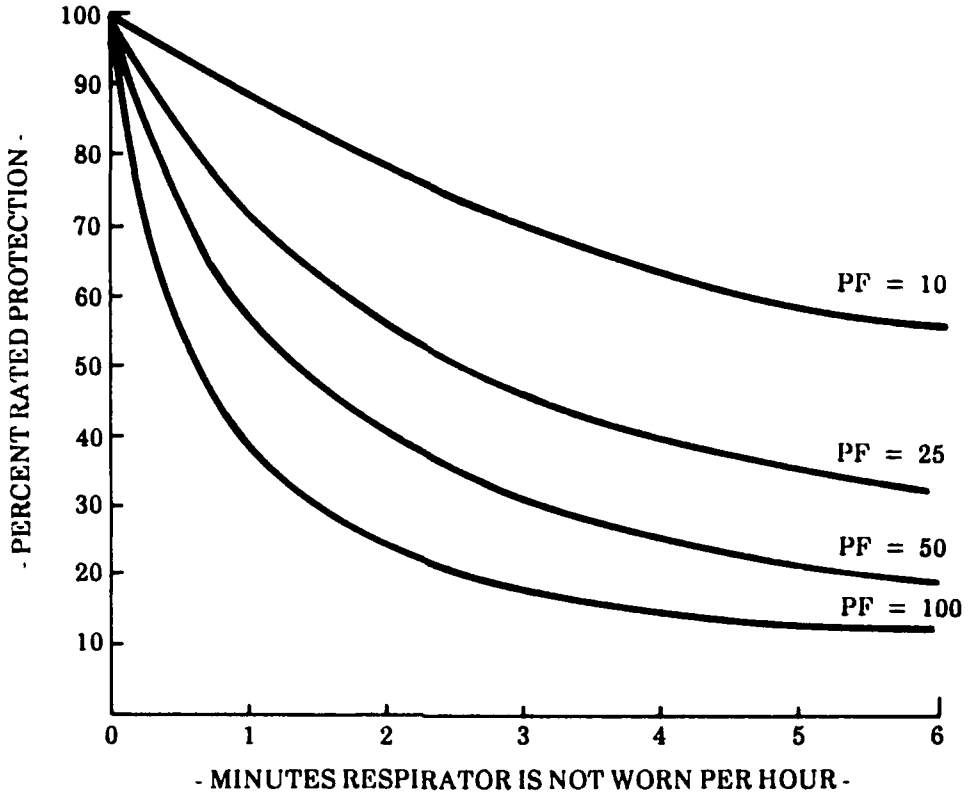
If $FF \geq 100$,

$$WUF = \frac{1}{\text{Time Not Worn (Fraction)}}$$

4. SOLID AEROSOL PARTICLE METHODS

4.1 NaCl.

A review of the NaCl method was presented by Mr. J. McCr adie that is summarized as follows. This method of QNFT was developed in the U.K. at Porton Down. It was chosen because it was already an established method for filter testing and permitted a range of aerosol concentrations to be produced



N.B. Data derived from

$$PF = \frac{\text{average contaminant concentration in ambient air}}{\text{average contaminant concentration inside respirator}}$$ for continuous wear

$$EPF = \frac{\text{average contaminant concentration in ambient air}}{\text{average contaminant concentration in inhaled air}}$$ time averaged

over periods of wear and non-wear

% RATED PROTECTION = (EPF/PF) x 100

---

*Frank Rosenthal, Ph.D.

Figure 2. Effect of "Non-Wearing" on the Effectiveness of Respirator Protection.

relatively easily. Additionally, it should be noted that NaCl at the concentration encountered either in the chamber or within the mask is not toxic to any extent for human subjects.

Two methods of generation of the NaCl aerosol were discussed. The original method was by high temperature sublimation from a "salt stick". In this method, a stick of NaCl is slowly fed to a flame that sublimes it to a vapor. Upon cooling outside the flame front, the NaCl vapor condenses to form aerosol particles. The range of aerosol mass concentration from such a generator, including dilution air to minimize coagulation, is from 25-45 mg/m^3.

Because this method requires some technical skill to produce a constant reproducible aerosol concentration, an alternative method of generation, nebulization of a NaCl solution followed by air drying, has been developed. Several different jet nebulizers have been employed for generations. The most common being a Dautrebande D30, producing an aerosol from a 1% NaCl solution with a mass median diameter (mmd) of 1.3 μm. When dried, the MMD of the NaCl particles is approximately 0.3 μm. This aerosol is polydisperse, having a geometric standard deviation of 1.7.

The concentration of NaCl in the chamber or mask cavity is determined by flame photometry. An air sample is pumped at a flow rate of 1 L/min. into a flame (either H_2 or propane). Sodium emission is detected by a photomultiplier whose selectivity to this emission is improved by optical band pass filtration.

The calibration of the photometer is important, especially for very low concentrations of aerosol that are sometimes realized in the mask cavity. The two methods of calibration employed are air dilution and nebulization of progressively more dilute NaCl solutions. The air dilution method requires accurate measurement of dilution flow; errors can be propagated in successive dilution to achieve dilution ratios > 1000. The dilution can be done dynamically by mixed flows or statically in a known volume.

The method of dilution by nebulization of successively diluted NaCl solutions has been employed, but is based on unproven assumptions. Calibration curves, especially at high dilutions (> 10,000) are questionable because the aerosol particle size changes at high dilution compared to 1% NaCl. Other factors such as charge and rate of evaporation may also

change. Employing the best methods of calibration, it was stated that protection factors could be fairly accurately measured up to 30,000.

The position of the sampling probe in the mask is important, since there is probably considerable variability of concentration despite a degree of convective mixing within the mask cavity.

This sample position must be standardized for a series of measurements or to compare data sets from different laboratories. Another factor of significance is the respiratory tract retention of the aerosol. It has been estimated for NaCl aerosol at normal breathing to be ~80%. Based on the dry diameter of the NaCl particles, the percent deposition for such size particles at normal tidal breathing for non-hygroscopic particles is 15%. Thus, the stated 80% deposition implies that the NaCl particles grow significantly by water accretion within the cavity and within the respiratory tract. This high percent deposition will have a significant effect upon the measured in-cavity concentration. It may also lead to deposition within the delivery lines to the analyzer.

4.2 Uranine.

The uranine method is similar to the NaCl method in many ways, including the generation by nebulizer, drying, and delivery. In contrast to NaCl or oil, the uranine aerosol cannot be analyzed in real time, but must be collected on a filter over a period of exposure and analyzed for mass by a fluorometric analysis. In the method used, in-mask sampling was performed intermittently and only during the inspiratory phase of breathing. This choice was not made because of the use of uranine. It was made because this procedure would avoid the problem of respiratory deposition and collect aerosol during the period when it was assumed that most peripheral leakage occurred.

The fluorometric method of aerosol mass analysis is very sensitive (0.1 ng/mL), so that leakage penetration of at least 0.1% (a protection factor of 1000) can be determined over a 15-min test period. A polydisperse aerosol of geometric mean diameter 0.2 μm was produced (σ = 2.0) from a jet nebulizer, but no measurement of growth or lung deposition has been reported.

4.3 BG.

The other solid aerosol method that has been used employs B. Globigii bacteria aerosolized from suspension in saline in the chamber. The bacteria concentration in the chamber is determined by light scattering. In the mask, the concentration is determined by collecting bacteria on a cotton filter in a brass holder held in the mouth. Thus, there is no mask sample taken from a particular region of the cavity, but it is assumed that the inspired air concentration is a measure of the mask concentration. As with uranine and NaCl, the growth within the mask cavity is not known. The bacteria itself has an effective diameter of 1.0 m, but the aerosol particles may contain more than one bacterium.

5. REVIEW OF FIELD TESTS FOR IN-MASK EXPOSURES

Laboratory QNFT using DOP test aerosol has been used to derive Fit Factors (FF) or Protection Factors (PF) (Peer Review Group felt that use of term Protection Factor is misleading and should be discontinued), (Tables 4 and 14) for general large groups or generic classes of respirators.

Specific FF data on individual manufacturers' products representing one class of devices, tested on a single group of test subjects, has been reported by Hyatt on Sodium Chloride (Table 16). These results represent the spread of laboratory FF achieved by the same individuals using different devices. Data are presented in terms of points on probability distributions. From discussions above, one concludes that substantial support has been directed to development and application of laboratory and POI test apparatus and procedures. Remember that these oil aerosol tests measure a more-or-less instantaneous penetration in a highly stylized fashion relating in no way to actual users' daily on-the-job experience.

Very little data are available on comparable interior/exterior contaminant concentration determinations in U.S. workplaces. Burgess,[7] at the NIOSH-sponsored Respirator Research Conference in 1980 says, "If I were forced to choose one research area and were asked to champion it at this gathering I would choose the study of the actual protection afforded by respirators in the workplace. This is obviously the bottom line in any respirator program. If one reviews the limited number of in-plant studies completed over past decades, one becomes concerned about the total impact of respirator programs on worker exposure. My first interest in this topic was generated at the

Table 16. Results of LASL QNFT on Test Panel.

No.	Respirator Tested	Persons on Panel	Type	Percent Panel with Leakage[5] Less Than		
				10.0%	2.0%	1.0%
1.	MSA Comfo II-Medm	35	1/2	91	80	69
2.	MSA Comfo II-M	25	1/2	100	100	100
3.	MSA Comfo II-Smal	25	1/2	84	72	64
4.	MSA Dustfoe 88	35	1/4	100	91	86
5.	Willson 1212	35	1/2	97	83	74
6.	Willson 500	35	1/4	80	57	40
7.	AO R-6057	35	1/2	37	20	20
8.	AO R-5057	35	1/2	80	74	74
9.	AO R-2000	35	1/4	86	69	60
10.	Glendale-2000	35	1/2	40	23	23
11.	Glendale-4000	35	1/4	91	83	80
12.	Pulmosan C-263	35	1/2	71	46	20
13.	Pulmosan C-264	35	1/4	83	29	14
14.	Cesco 94	35	1/2	89	80	71
15.	Cover-No Chin Cup	35	1/2	91	71	71
16.	Cover-No Chin Cup	25	1/2	100	72	64
17.	Scott-L	25	1/2	93	86	86
18.	Scott-S	25	1/2	93	71	68
19.	Norton 7580-L	25	1/2	84	68	60
20.	Norton 7580-M	25	1/2	96	92	88
21.	Draeger R27-201-L	35	1/2	43	31	31
22.	Draeger R27-202-M	35	1/2	86	74	74
23.	Draeger R27-203-S	35	1/2	89	74	57

1968 American Industrial Hygiene Conference when Caldwell and Schnell displayed dismal protection factors in the application of half mask air-purifying respirators for protection against uranium dioxide.[3] The authors concluded that 'air-purifying half-face respirators are supposed to provide better than a factor of 10 protection. The computed average for the data shown is 2.1. These data were based on biological monitoring and therefore effective protection factors and not conventional protection factors were calculated in this study.'

"A field study by Revoir to evaluate single use respirators against cotton dust revealed more impressive protection factors ranging from 8 to 84. In a NIOSH sponsored study of respirator use in abrasive blasting, Blair has shown the large variability in protection encountered in the use of air supplied respirators. These devices are normally considered to provide excellent protection with a protection factor of 2,000."

"Where air supplied helmets were used, protection factors from 1.9 to 3750 were noted. The remarkable range of these later figures is attributable to the condition of the individual equipment rather than to any particular brand superiority."

"Additional evidence of the limited effectiveness of air supplied hoods used in sandblasting has been provided by Samimi."[9]

"In a study of dust respirator performance in coal mines conducted by Eastern Associated Coal Company in cooperation with the Harvard School of Public Health under a NIOSH contract, the same pattern was revealed with lower protection obtained than predicted by application guidelines. However, this study evaluated effective protection factors and introduces the issue of effective choice of use time by the wearer." (See reference to Harris, et al., in Table 17.)

"A study of the paint spray industry revealed that conventional air-purifying paint spray respirators provided an average protection factor of 3 for vapors and not the 10 that one might anticipate from the protection factor tables. In the case of air supplied half masks, the observed protection factors ranged from 3 to 30, and not the 1000 one would expect from the guidelines."

"In a study of in-plant respirator protection factors for protection against sulfur dioxide in copper smelters, Moore

Table 17. Effective PF During Actual Use.

Study	Job Site	Measured	Respirator	No. Workers (No. Measuremts)	Total Time	External Conc.	Respirator Worn	Effective PF	Reference
Harris et al 1974	Bituminous Coal Mines	Respirable Coal Dust	5 Models Dust Respirators	21 (89)	4-5 days Full Shift (Ex. Lunch)	1.8 mg/m^3	51 Min. (42-60)	5.6 (3.2-9.0	1
Revoir 1974	Cotton Textile Plant	Total Dust Closed Sampler on Mask	Styles Single Use dust resp.	5 (16)	2 hrs. Excessive Moisture	2.8 mg/m^3 1.1-6.7 High Dropped Open Sampler	2 hours	33.8 (8.0-83.5	2
Blair 1975	Abrasive Blasting Monuments Shipyards, Painting Prim. Metals	Respirable Dusts	Both Supplied Air Hoods and Plain Dust Masks incl. rag	(110)	1-7 hrs. on 5	18.4 mg/m^3 1.6-82.0	During Measurement	49 < 10PF (2.1-630)	3
Moore et al 1976	Copper Smelter	SO_2	3 half-mask Chemical Cartridge	9 (76)	80 Min.	55 mg/m^3 16.1-196.1	80 Min	12.9;18.4; 22.4 (2.6-83.1)	4
Toney et al 1976	Spray Paint Booths	Solvents Aerosols Particulates	15 Types Painters Own	(40)	10 Min.		10 Min.	-	5
Smith et al 1980	Cadmium Production	Cd	15 Types Most ¼-½ Masks	9 (27)	3 consec. days Full Shift Incl. Lunch		not recorded	-	6

1. Harris, H.E., W.C. DeSieghardt, W.A. Burgess, P.C. Reist: Respirator Usage and effectiveness in bituminous coal mining operations. Am. Ind. Hyg. Assn. J. 35 (3): 159-164 (1974)
2. Revoir, W.H.: Respirators for protection against cotton dust. Am. Ind. Hyg. Assn. J (35) (7): 503-509 (1974)
3. Blair, A.W.: Abrasive blasting protective practices study-field survey results. Am. Ind. Hyg. Assn. J (36) (10): 745-751 (1975).

Also see NIOSH Report No. 74-104 (1974)

4. Moore, D.E., T.J. Smith: Measurements of protection factors of chemical cartridge, half-mask respirators under working conditions in a copper smelter Am. Ind. Hyg. Assn. J 37 (7): 453-458 (1976).
5. Toney, C.R., W.L. Barhart: Performance Evaluation of Respiratory Protective Equipment Used in Paint Spraying Operations. NIOSH 76-177 NIOSH Cincinnati (June 1976).
6. Smith, T.J., W.C. Ferrell, M.O. Varner, R.D. Putnam Inhalation exposure of cadmium workers: effects of respirator usage: Am. Ind. Hyg. Assn J 41 (9): 624-629 (1980)

showed that the protection afforded by three different half mask respirators was quite variable with mean protection factors of 22, 18, and 13. Although the mean values exceeded the guideline protection factor of 10, the best respirator had 30.4% of its tests with factors less than 10, and the worst had 56% with factors less than 10."

"Smith had evaluated the effective protection factors (EPF) provided by intermittent use of a combination acid gas and metal fume respirator and a filter respirator for protection against cadmium. A wide variability on protection was demonstrated with a geometric mean EPF of 5.6. One worker in this population was atypical of the group. He was fastidious in the use of his respirator and obtained consistently high protection factors. If his data are not included, the geometric mean EPF becomes 3.9 and approaches the 3.2 noted by Harris."

Data on average exposure to carbon monoxide (CO) of Baltimore fire-fighters has been presented by Levine.[10] He found through measurements of blood COHb that demand mode SCBA's give a biological effective protection factor (or penetration measured through biological uptake) of about (2.5-0.5)/(1.5-0.5)=2, as indicated in Table 18 for non-smokers. These data agree with data on laboratory performance of demand mode. The conclusion was drawn that SCBA in demand mode (negative pressure in cavity to initiate flow) should NEVER be used (Table 19).

At this workshop, Warren Myers presented data from field studies conducted over the past 2 yr by the DSR testing and Certification Branch, NIOSH. The work included a limited field study on a tight fitting facepiece powered-air-purifying-respirator used for protection against silica dust, and two major field research studies on respirators used for protection against lead dust and lead fumes. Table 20 summarizes the data.

The results show that the protection factors measured at the industrial workplace (W.P.F.) for the PAPR were significantly less than the assigned PAPR protection level of 1000. On the other hand, the workplace protection factors provided by the half-mask NPR in both work areas of its use were significantly greater than the assigned half-mask NPR of 10. Users of the half-masks were reported to be very knowledgeable and conscientious about their use of the mask.

Preshift quantitative fit factors were determined but no correlation with the workplace protection factors could be established.

Table 18. Biological Indications of SCBA* PF in Baltimore.[10]

Category	Blood Carboxyhemaglobin Con. %*
Non-Smoking Fire Fighters - Background	0.5% (endogenous and urban environmental background)
Non-Smoking Fire Fighters - at Fire Scene, No RPD	2.5%
Non-Smoking Fire Fighters - After wearing SCBA** At Fire Scene ("Always Use")	1.5%
One-Pack a day Smoking Fire Fighters - Background due to Smoking alone	5.0%
Smoking Fire Fighters - After Wearing SCBA** at Fire Scene	7.5%

*None of the concentrations found are of special health significance

**Demand Type

Table 19. SCBA Tests on DOP and NaCl.

A. FREQUENCY DISTRIBUTION OF FACEPIECE LEAKAGE OBTAINED BY SUBJECTS TESTING SCBA.* COMPARISON OF 31 FIREMEN PANEL VS 25 PERSON MALE AND FEMALE PANEL

Manufacturer and Type Full Facepiece	Year Tested	No. Subj.	Percent of Subject with Leakage Less Than % Listed					
			0.01	0.05	0.1	0.2	1.0	2.0
1. MSA								
a. Clearvue	71-72	31	52	74	87	97	97	100
b. Ultravue	71-72	31	74	77	84	97	97	100
c. Ultravue	78	25	4	12	32	44	80	92
2. Scott								
a. Old Scottoramic	71-72	31	13	48	58	68	90	100
b. New "	71-72	31	10	23	48	74	84	100
c. New " 742	78	25	4	4	24	40	96	96
d. 4.5 Plastic	78	25	0	12	28	28	60	64
3. Globe								
a. Sierra-N	71-72	31	26	65	81	97	100	
b. Sierra	78	25	0	0	8	12	48	55
4. Survivair								
a. D/PD-Silicone	71-72	31	58	77	88	94	97	97
b. D/PD-Neoprene	71-72	31	0	19	39	71	87	94
c. D/PD	78	25	4	4	16	28	68	72
d. D Only	78	25	0	4	12	24	76	84

*SCBA in Demand Mode (Negative Pressure)

B. FREQUENCY DISTRIBUTION OF PERCENT FACEPIECE LEAKAGE OBTAINED BY PANEL DURING 77-78 LASL TESTS ON SAME FULL FACEPIECE USED WITH 1) AIR-PURIFYING (A-P), 2) SUPPLIED-AIR (S-A) IN DEMAND MODE, AND 3) SCBA IN DEMAND MODE

Manufacturer and Type of Full Facepiece	No. Subjects	Aerosol	Accumulative % of Subjects with Facepiece Leakage Less Than % Listed						
			0.02	0.05	0.1	0.2	0.5	1.0	2.0
1. MSA									
a. A-P, UV, Twin	35	NaCl	46	86	97	100	100	100	100
b. S-A, UV,	25	DOP	4	16	20	44	72	88	96
c. SCBA, UV	25	DOP	12	20	32	44	68	80	92
2. Scott									
a. A-P, 742	35	NaCl	57	83	86	91	91	97	100
b. S-A, 742 Std.	25	DOP	8	8	20	20	28	68	92
c. S-A, 742 Tite	25	DOP	0	12	20	24	32	40	56
d. SCBA, 742	25	DOP	4	4	24	40	72	96	96
3. Sierra									
a. A-P, Welsh	35	NaCl	31	49	51	69	93	83	89
b. S-A, Globe	25	DOP	0	0	0	4	12	20	28
c. SCBA, Globe	25	DOP	0	0	8	12	40	48	56

Table 20. NIOSH Field Data.

Industrial Exposure	Respirator Manufact.	Type	Air Purifying Element	No. Of Subjects/ Tests	POI ONFT	Count Median W.P.F.	Geom. S.D.	Range W.P.F.	"Rated" P.F.
1. Silica Flour Baggers	MSA	PAPR (½ Mask)	HEF	NS		54	2.24	16-215	1000
2. Lead Batt'y Plant	3M (W-316)	Helmet PAPR	D&MF	23	-	116	2.62	76-175	NA
a) Plate Mnr.	Racal (AHS)	"	"	23	-	119	2.66	23-1053	NA
b) Secondary Lead Smelter	3M (W-344)	Helmet PAPR	HEF	22	5100	165	3.57	28-5)00	1000
	Racal (AH3)	Helmet PAPR	HEF	21	7900	205	2.83	42-2323	1000
3. Lead Primary Smelter	MSA	NPR (½ Mask)	HEF	7	-	450	3.1	110-2200	10
a) Sinter plant	MSA	PAPR (½ Mask)	HEF	7	>1000	330	3.7	23-930	1000
b) Blast Furnace area	MSA	NPR (½ Mask)	HEF	18	-	130	4.0	10->1700	10
	MSA	PAPR	HEF	18	-	400	2.3	94-1600	1000

N.B.: Definitions and abbreviations used in this table include:

W.P.F. = Workplace Protection factor

"Rated" PF = Assigned Protection Factor for the given respirator type

HEF = High efficiency filter, 99.97% efficiency, 0.3 μm DOP

D & MR = Conventional dust and mist filter tested on silica certification

PAPR = Powered air-purifying respirator

NPR = Non-powered respirator, i.e., a conventional lung-powered air-purifying respirator

The result of these studies are currently being prepared for publication.

The general conclusions from this review and from presentations and discussions at this meeting are: (1) further effort should be directed to the development of field test methods and field performance factors (FPF) and (2) field performance factors determined using a concentration averaging sampler system over extended periods at point of use do not agree with POI FFs and are nearly always found to be lower than POI FFs and the generic PF for class of device.

6. GAS OR VAPOR TEST

One of the issues that arises when considering the current status of testing to determine respirator POI or POU is what test method to use. We have reviewed above a number of findings and observations on solid or liquid aerosol particle test systems and field results on NO_2, coal dust, cotton dust, abrasives, SO_2, spray paint solvents and particles, Cd fume, CO, and Pb fume and dust. It is immediately evident that comparisons between the various lab or POI fit tests do not agree and field results do not agree with lab data. We have expressed the opinion that there is no reason why solid or liquid aerosol particle tests should agree, and further, no reason why either of these should agree with a gas or vapor test because the mechanisms and kinetics of removal are different for each of the substances, by the leaky respirator components or face mask interface, and by uptake in the respiratory system. Attempt to demonstrate equivalence between various aerosol fit tests and gas and vapor fit tests have been conducted over the past 20 yr. Apparently there have been no organized efforts to provide any kind of round-robin testing to determine differences in data from each test system user. There are no absolute (airborne mg/m^3) calibrations on any test systems.

Table 21 summarizes several of these issues. Table 21A presents a brief summary of the major historical milestones in the development or use of various aerosol systems (also see Table 2 for an historical overview summary of respirator tests).

Table 21B presents a summary of gas and vapor test agents that have been described in technical literature. The only method currently available commercially in the U.S. for gas and vapor leakage testing is the National Draeger system described in Appendix E. Data on comparative leakage factors with DOP and gas are presented there. The method is simple,

Table 21. Test Materials Used for Leakage Tests.

Substance	Date	Investigator, Remarks
A. Particulate Test Materials		
Thermal DOP	1940-45	Developed by US Army and Navy (NRL) for high-efficiency filter testing (0.3 μm).
B.globigii	1954	Guyton, Lense, Decker; BWL Ft. Detrick, 1 μm spores.
Uranine	1959	Silverman, Burgess, Stein, Corn; Harvard SPH, CMD = 0.2 μm, σ_g = 2.4, MMD = 2.4 μm, C_{ext} = 4 mg/m^3, 2.3% sol'n gen., detect 10^{-9}gm/ml in 10 ml sample.
Thermal DOP (MDOP)	1960	U.S. BOM, monodisperse, LSCMD $\tilde{=}$ 0.3 μm, σ_g < 1.5.
	1965	U.S. BOM, Sched. 21B describes use of TDOP & Uranine for certification tests on filters
NaCl	1962	Hounam, UKAEA Harwell, AERE-R4125, nebulizer.
	1965	White, Canadian AERE, salt stick (?).
	1969	Burgess, HSPH, CMD = 0.2 μm, σ_g = 2, C_{ext} = ?, human subjects on bicycle ergometer at 4.5 kg-m/min.
	1970	Dorman, Porton, Brit. Std 4400-69, 2091-69.
	1971	Persson, Sweden.
——	1972	NIOSH adopts BOM schedules for respirator certification, recodifies, drops DOP and uranine tests.
Thermal DOP (MDOP)	1971	LASL (LANL), Hyatt, Mitchell, Bevis, develops 0.3 μm test system for NIOSH, begins human tests, problems with subject complaints of odor, irritation.

Table 21. Test Materials Used for Leakage Tests (Continued).

Substance	Date	Investigator, Remarks
Cold DOP (PDOP)	1971	LASL (LANL), Hyatt et al., develops cold air-nebulized test system with CMD = 0.6, σ_g = 2, C_{ext} = 25 mg/m^3 in 75 cfm, dynamic range to 10^{-4} mg/m^3 Pen. 0.01%.
NaCl	1975	LASL (LANL) for NIOSH, systems now made comm'l by ATI and Frontier.
B. Gas or Vapor Test Materials		
H_2S, SO_2	1955	Hoelscher, Hopkins Chem. Eng. Dept.
Freon 12	1962	Frank Adley US AEC-HW.
	1963-64	F-12, 114, MSA for US Army 65-70 Rockwell.
	1978	Packard, AIHAJ 39:723. Dow Training w/mouthpc resp. esc.
	1964	Morgan UK AERE-R4484.
	1970	Bumines RI 7431 Watson F-12 See Clark CDE JISRP 1(2), 77 (83) quadrapole mass spec.
SF_6	1970 (78)	LASL LA-7317-PF = NIOSH 78-161.
	1979	Inouye, Japan.
N_2	1964	Dorman, Porton.
He	1975	Cyr, U.S., J. Vacuum Sci. Tech 12 419, 1975
Ar	1970	Griffin, UK, AOH 13:147 . Dorman, Porton uses quadrapole mass spec. Also see Clark CDE (above).
Parafin oil	1979	Balieu, Denmark, J. Intl. Soc. Resp. Prot. 1, 125, 1983
n-Pentane	1976	deStergeur, US.
Ethylene	1980	Draeger US, Germany.
	1978	Pasternak.

Table 21. Test Materials Used for Leakage Tests (Continued).

C. Comparative Performance Tests Using Aerosol, Gas or Vapor Test Materials

	Test Materials Compared	Respirator Type	Result of Test	Reference
1.	Cold DOP (1.2 μm) vs. NaCl (0.6 μm)	Fume Resp.	NaCl Pen. =.006 DOP Pen. = .004	Hyatt,1973
2.	SF_6 vs. DOP vs. NaCl	-	"no clear trend" NaCl ≈ SF_6 ≈ DOP	Lowry, 1977
3.	Cold DOP vs. NaCl	Half Face	DOP Pen. > NaCl Pen.	Wallendorf, 1980
4.	N_2 vs. NaCl	MK 7	N_2 Pen. ≈ NaCl Pen.	Dorman, 1964
5.	F-12 vs. NaCl	-	F-12 Pen.< 0.2% NaCl Pen < 0.01%	Houmann, 1964
6.	Argon vs. NaCl	-	no trend	Griffin & Webb, 1970

inexpensive, and field portable. As indicated in Table 21B, although seven gases and vapors have been used, apart from the commercial ethylene test system of Draeger only Freons(R) have received much acceptance. Freon(R) 12 (dichlorodifluoromethane) or sulfur hexafluoride is currently under consideration as a standard by the ASHRAE for laboratory exhaust hood acceptance testing, using a MIRAN(R) -1A infra-red analyzer. The stated detection limit for F-12 with this instrument is 0.01 ppm. Hood challenge concentration is of the order of 100-1000 ppm, so detection is of order 10^{-4} to 10^{-5} dynamic range (TLV(R) is 1000 ppm). Freon(R) uptake by the body during inhalation is easily measured by serial analysis of alveolar end-tidal air samples. Thus, separating the problem of uptake (or deposition) on inhalation from cavity-mixing on exhalation (e.g., see Stewart and Petersen's classic study).

Table 21C presents a summary of results of comparative tests of aerosol-aerosol or of aerosol-gas/vapor for respirator leakage determinations. Although early studies of DOP and NaCl seemed to indicate little difference, most recent tests indicate DOP pen > NaCl pen, consistent with theoretical expectations. Wallendorf's test results[5] at LASL (LANL) in 1978-79 on equal sized Cold DOP (PDOP) and NaCl (MMAD = 0.6 $\pm$ 0.2 μm σ_g = 2.0, C_{ext} = 25 $\pm$ 5 mg/m^3 for PDOP versus MMAD = 0.66 $\pm$ 0.12 m, g = 2.2, C_{ext} = 15 $\pm$ 2 Mg/M^3 for NaCl), are indicated in Table 22. Differences on individuals are not great and are much greater between individuals on a single mask or between masks.

Differences between aerosol (NaCl) and gas (SF_6) test results from LASL (LANL) have been summarized by J. Boardway, U.S. Army CSL in a private communication (1983), as shown in Table 23. Lowery of LASL (LANL) stated in 1979 (LA-6722) that there was "no clear trend" in human exposure tests. Tests on a breathing machine-headform with demand SCBA indicated that NaCl penetration = SF_6 penetration. Charcoal retention or capacity for SF_6 is poor, it is not held well by charcoal, apparently.

As a general conclusion, one finds that leakage differences determined between any two materials in laboratory tests tend to be smaller than inter-subject or inter-respirator differences. No clear trends are apparent. No major theoretical or experimental fundamental study has yet been found. There are no reasons why leakage should be the same for two different materials.

Table 22. Half Mask Penetrations for Fit Test with DOP and NaCl[4].

Test Subject	Respirator A		B		C		D	
	DOP	NaCl	DOP	NaCl	DOP	NaCl	DOP	NaCl
EZ	0.16 (0.02-0.27)	0.11 (0.05-0.21)	5 37 (0.10-10.6)	2.78 (0.07-7.3)	0.75 (0.27-1.6)	0.22 (0.17-0.30)	2.4 (1.3-3.2)	1.47 (0.41-2.5)
JM	0.05 (0.03-0.07)	0.04 (0.03-0.06)	0.25 (0.15-0.31)	0.09 (0.04-0.14)	5.0 (3.5-7.4)	0.60 (0.47-0.71)	34.6 (30.4-41.7)	20.5 (18.0-23.8)
DM	12.3 (3.3-20.9)	10.3 (1.7-16.3)	22.0 (11.2-30.7)	12.2 (5.9-18.7)	1.15 (0.58-2.2)	0.50 (0.34-0.62)	33.7 (28.0-37.9)	15.1 (6.5-23.2)
JJ	1.51 (0.05-4.4)	0.17 (0.05-0.40)	20.9 (11.9-29.9)	9.50 (4.9-16.0)	0.76 (0.57-0.87)	0.35 (0.20-0.61)	3.2 (0.34-8.4)	2.3 (0.42-5.8)
NK	16.2 (4.0-28.7)	14.7 (2.8-23.4)	34.8 (16.6-44.8)	21.4 (11.0-28.1)	0.74 (0.31-1.33)	0.15 (0.10-0.21)	1.7 (0.[illegible]-2.6)	1.4 (0.09-2.6)

Table 23. Vapor/Aerosol Leakage Correlations Parameters.

SF6 vs NaCl and DOP (NIOSH/LASL, 1977)

Results:

Test		Penetration (%) NaCl	DOP	SF6	Comments
Man Tests	n = 50 n = 5	All indicate < 1 to > 10			Differences between agents
	> 1%	4.0	4.6	4.6	masked by variation within each test (10 subjects, 5 tests each)
Headform Test w/Breather Pump	x	5.0	4.17	5.1	Six replicates - indicates good correlation (1/8" x 1" capillary leak)
	s	0.37	0.31	0.26	

CONCLUSIONS:

1. "Since the NaCl and SF_6 results (controlled leak bench tests) are in excellent agreement, it was concluded that aerosol and gas test agent leakages should be equal when these agents are used to determine respirator protection factors."

2. "These results show that a respiration PF obtained with an aerosol...is valid when...used in a gaseous contaminant. This means...approval criteria need not include both aerosol and gaseous quantitative fit tests..."

7. CRITERIA AND POTENTIAL METHODS FOR NON-INTRUSIVE RESPIRATOR QNFT MEASUREMENT

A presentation of the type of leakage tests that do not require penetration of the mask is summarized as follows. Desirable characteristics or criteria for acceptability are shown in outline form in Table 24. If the QNFT is to be used in the field or away from a laboratory, the system must be portable and consistent with available electric power. When used as a POU or for numerous subjects, it must be easy to operate and provide the requisite sensitivity for in mask concentration measurement.

Table 24. Parameters for Non-Intrusive Test Methods.

1.	Portability
2.	Ease of Performance
3.	Sensitivity
4.	Specificity
5.	Accuracy
6.	Precision
7.	Approximation of Working Conditions
8.	Engineering Specifications
9.	Safety
10.	Cost
11.	Integrated vs. Real Time Results
12.	Interior vs. Exterior of Mask Cavity
13.	Temporary vs. Permanent Modification

The method of analysis must also be appropriately specific, accurate, and precise. The placement of a measuring element either within or on the respirator must not interfere with its functional use in working conditions appropriate to the user. It must be safe to use and not entail excessive cost.

Most desirable is a sensor that gives real time simulant (gas or aerosol) concentration information, as does the light scattering instrument, since it is apparent that the cavity concentration varies during the respiratory cycle. However, if a suitable simple method (such as a paper tape indicator) can be developed that is an indicator of integrated dose during the test period, this would probably be acceptable for field testing.

The issue of whether the sensor should be exterior or interior to the mask cavity was discussed. An interior sensor would have to record information or transmit it to the exterior,

either by telemetry or by hard wiring. Hard wiring again appears to raise the problem of mask penetration, but if the wiring connection could be incorporated into the mask molding, this could probably be accomplished without loss of integrity.

This question of exterior or interior sensor is also relevant to the issue of whether the sensor should be permanently mounted in the respirator or be a temporary insert. If retest is desired, it may be desirable to have the sensor permanent, if it can be assumed that no degradation of its performance will occur over the respirator lifetime.

Table 25 is a list of the methods presented and discussed. These include methods in which the dose of a test substance is determined by a biological assay such as urine, blood, or skin test. The analysis, done by collection of respiratory exhalate, is also a type of "bio assay", somewhat less invasive than blood sampling. The list is organized according to sample collection, sample analysis, and data recording and transmission.

During the presentation and discussion outlined above, numerous comments were offered. These have been organized into five groups, dealing with: (1) the necessity of non-intrusive tests (NITs), (2) the definition of "non-intrusive", (3) suggested parameters for evaluation of NITs, (4) suggested methods, and (5) the means of categorizing these methods.

What was probably the most important discussion centered around whether or not NITs were really needed at all. Proponents noted that by testing individual masks on individual wearers, unencumbered by tubes and able to perform their work routine, WPFs can more accurately be determined. In addition, being able to show an individual what happens when he dons his particular mask would be a positive training aid and would enhance motivation to wear the respirator. A reference was also made to unknown interactions involved with extracting samples from the mask cavity. On the other hand, those who felt NITs unnecessary argued that the variability in other aspects of QNFT would swallow any variability between respirators of the same manufacture.

Throughout the beginning of discussions there appeared to be some vagueness about what "non-intrusive" was intended to mean.

Table 25. Methods of Non-Intrusive QNFT.

Sampling Methods

1. Permanent Valve
2. Exhalate Analysis
3. Urine analysis
4. Blood Analysis
5. Paper Tape Dosimeter
6. Passive Dosimeter

Analysis Methods

1. Colorimetry
2. Light Scattering of Aerosol
3. IR Spectroscopy
4. UV Spectroscopy
5. Magnetic Detection
6. Gas Chromotography
7. Radioactive Detection
8. Solid State Colorimetry
9. Thermal Conductivity
10. Skin Conductance
11. Skin Visual Analysis
12. Eye Surface Analysis

Data Recording and Transmission Methods

1. Integral Hard Wiring
2. Optical Transmission (eyepiece)
3. Telemetry

The general consensus seems to be:

- The method should in no way alter the integrity of the mask (the respirator should be suitable for field use after the test)
- it should be small enough so as to be "non-obtrusive" to the wearer
- it should allow the subject to perform his normal routine without interference for test materials.

From this "Blue Sky" definition, a number of implied parameters arise in addition to those overtly stated in the discussion. The system should be totally enclosed within the mask cavity with no connections external to the respirator. Some form of telemetry would be important here. This would necessitate a sensitive, miniaturized system that would remain in the cavity practically unknown to the wearer. It should be either impervious to or protected from the high temperature and humidity conditions of the cavity and should give a real time response in order to be able to differentiate where peak doses occurred and how inhalation or exhalation affect leakage. This would also indicate an active rather than a passive system.

While these parameters outline an optimal situation in the future, suggested methods addressed not only that aspect but present limitations as well. The first was some sort of permanent valve that could be capped when not in use; this raised objections to the idea of putting yet another potential leak into the mask. Implanted passive personal dosimeters could not differentiate between inhalation concentration and those present during exhalation. An in-mask filter in the form of a mouth plug was suggested, but this could hardly be called "non-obtrusive" to the wearer. Colorimetric paper assays raised the most common objective of all: it is not sensitive enough.

Finally the view was offered that the methods should be recategorized into methods of collection (or sampling), methods of measurement, and methods of recording the data, all three being incorporated into a single system.

8. WORKSHOP ON IMPROVEMENTS NEEDED ON CURRENT METHODS

The workshop on improvements needed in current methods was led by H. Ettinger (LANL) with participation by J. Pritchard, J. Agarwal, J. Boardway, and C. Billings (Reporter). The working group first identified current methods of human fit/leakage testing as aerosols, oil mist (DOP/DOS/Corn Oil); NaCl (nebulized by Dautrebande, Collision, or thermal salt-stick vapr/condn); B. globigii; and possibly paraffin oil (described in some German articles); and gases/vapors: SF_6; Freons(R); and ethylene. After consideration of the amount of experience in use of these methods and specific objectives of the proposed applications, consideration was restricted to DOP, NaCl, and BG.

The next area of workshop discussion related to needs in the area of apparatus and procedures for its use, including generation, sampling and analysis, calibrations, Q/A,

dissemination or transport system, type of chamber or hood, and methods for selecting representative subjects, protocol for test procedures or test plan, and exercises to be used. These were considered in terms of the purpose of the test and the point or location of the testing (e.g., research and development in a laboratory versus field tests for face fit or risk analysis on groups of wearers, shelf life surveillance, Q/A, etc.).

The area of unknowns or limitations of current practice was explored next. These included questions of possible toxic hazard in interactions with subjects, and interactions of test materials with materials of construction of the respirator or of components of the measurement system (e.g., use of a vapor test on charcoal is likely to be a destructive test requiring replacement of cartridge). The need for fit factors or field performance factors greater than about 10^4 was discussed. These estimates for agent effects are necessarily limited to subpathologic although physiologic changes may be used in a limited way with physically fit and trained users (e.g., CS). Non-invasive test apparatus and procedures that would not compromise device integrity would be desirable, if possible. There was a general agreement that standard methods, apparatus, procedures, protocol, and exercise regimen would benefit from research. Air sample size (1-5 Lpm now) continues to provide an unknown amount of leakage. (The question of sampling only on inhalation with a cavity mounted collector as done by Silverman and Burgess in 1959 was not discussed.) (The need for real-time instantaneous read-out versus a 5-10 min wait for removal and analysis as with dye aerosol was also not considered). There is a general agreement that particle size analysis needs to be conducted on a continually scheduled basis, with periodic rechecks and instruments for this needed research. An approximate particle size has not been selected, except what has been thought to be needed, but no research has been done on the particle size of leaks. (Particle size of maximum penetration will probably be different in this application than was developed for space filters with HEF media). The location (geometry, shape, etc.) of sampler inlet within the mask cavity has never been investigated as to its size selectivity or its ability to extract a representative sample. This bears, of course, upon the question of contaminant flow and distribution within the mask cavity and the nature of the effect under consideration, and what the target issue for effect is (e.g., the eye versus URT/LRT pulmonary gas exchange, etc.). Sampler design, line length and line losses, and configuration were also judged to be unexplored and their effects unquantified to date.

There was a reiteration of the need to explore laboratory or POI data relationships to actual FPF/WUF/MUC in the field at POU. The definition of terms need discussion and agreement. Standards for appropriate exercises need to be explored, developed, and proposed for review and opinion. The statistical interpretation of test data is in a deplorable state, and bears directly upon the practical consideration of the costs of protection versus benefits and acceptable risk to those overexposed.

The deliberations of the working group and recommended research items are summarized in Table 26. Needed research is grouped into three broad categories:

- I Apparatus and Procedures
- II Test Protocol
- II Date Analysis and Interpretation

9. WORKSHOP ON NEW METHODS

The purpose of this workshop session was to identify, discuss, and prioritize research and development needs related to new methods for respiratory QNFT. It was recognized at the outset that the current methods of QNFT are basically laboratory methods and that the only practical field test methods presently used are qualitative in nature. Thus, before new methods could be developed for POI or POU (field) tests, it is necessary to establish operational requirements for such methods. Only when such requirements have been agreed upon by the users can the approaches which best fit these requirements be developed for the list of possible methods.

The workshop participants discussed in detail the lack of information on aerosol parameters and their influence on leakage. The aerosols that are currently used for QNFT have been chosen for convenience; they are for the most part, the same aerosol systems chosen for filter testing. The size of such aerosols was chosen for filter testing to give what was presumed to be maximum penetration of the filter. There is no reason to assume that an aerosol that gives maximum penetration through a fibrous filter will give maximum leakage through a respirator face seal or components.

Table 26. Improvements to Current Methods.

I. Apparatus and Method for Substance Generation, Delivery

1. Toxicology of Oils
2. Characterization of Aerosols (size, charge, etc.)
3. Behavior of Monodisperse vs. Polydisperse Aerosol
4. High Output Generation
5. Standardization of Generation of Aerosol
6. Non-Intrusive Test of Current Substances
7. Probe Location Effects
8. Distribution of Contaminant in Facepiece
9. Location of Major Leaks for Facepiece
10. Automated Sampling
11. Faster Response Instrument for Concentration Measure
12. Linearity of Light Scattering/Flame Photometer Instruments
13. Chamber Design: Size, Shape
14. Recording and Computing - A/D Converter

II. Test Protocol

1. Standardized Definition of Protocol
2. Arrangement of Exercise
3. Standard Anthropometric Criteria
4. Improved Training Techniques
5. Environmental Effects on Test Results

III. Data Analysis and Interpretation

1. Dose vs. Peak vs. Pass-Fail Criteria
2. Reproducibility
3. Relationship of POI (PF/FF) to POU (FPF, WUF)
4. Small Number Statistics
5. Risk Assessment of Data

The participants identified the effect of particle size and other particle parameters (e.g., charge, physical state) upon respirator penetration as a significant gap in knowledge and a major need for research. Particularly lacking is any information on particles smaller than 0.1 μm and particles larger than 5 μm. However, it was agreed that the entire spectrum of sizes ought to

be systematically investigated. It has been tacitly assumed in past studies that a single aerosol, be it oil or NaCl, could serve as a suitable surrogate for all aerosols and vapors. The practicality of this hypothesis needs to be determined.

In order to accomplish these studies, methods of measuring aerosol size distributions both inside and outside a respirator need to be developed. This raises the further issue of the possible differences in size distribution of the outside and inside aerosol. It has been assumed that the fraction of aerosol penetrating the respirator has the same size distribution and thus can be measured in the same manner to obtain a concentration ratio. If this is not true, then the measurement of concentration, especially if by light scattering, is flawed by the presence of particles that either under or overestimate concentration.

The psychological factors that influence respirator usage have been identified as an important gap in knowledge and an area for needed research. This was emphasized in the presentation by H. Ettinger on oil aerosol method. A relationship was derived demonstrating the effect of exposure without respiratory protection on the "effective protection factor" of an 8-hr exposure period. Even if the "protection factor" or respiratory protection is very high, the effective value is markedly degraded if the fraction of time without protection becomes appreciable (> 10%).

Needed research in this area includes study of the motivation for long term continuous use of respiratory protection as well as the short term use of a respirator when an immediate need for protection is evident.

The use of aerosols as surrogates for vapors is another area perceived by the participants to be of importance as a research topic. Two major questions were raised: (1) is an aerosol an appropriate surrogate for vapors with respect to respirator leakage, and if so, (2) what size and composition of aerosol gives the best approximation of vapor leakage? Few studies in the literature or elsewhere have addressed this issue and none have carried out studies where the measurements were made simultaneously. The widespread use of aerosols as test agents even when vapor exposure is the only hazard makes this an important and relevant area for study.

Another important area for research is the practical upper limit of concentration ratio for respiratory protection.

Factors > 100,000 have been reported in some studies. This requires that the concentration method of whatever agent used must be accurate over a 5 to 6 order of magnitude range. Practically speaking, even if an instrument has the desired sensitivity, it must be calibrated by a dilution method over this range. There is a need to develop accurate dilution methods up to 100,000X for aerosols and vapors that can be independently verified. Both the oil and NaCl methods of aerosol analysis have not been accurately calibrated to a concentration for factors > 100,000.

Up to now, studies of respirator fit have identified physical factors appearing to be related to leakage. These physical factors include strap tension, head movement, body movement, body position, or acceleration. There is a need for more quantitative and systematic studies of such factors that have been described only qualitatively in the past. As well as testing the entire respirator in motion, there is a need to determine the effects of work related motion upon components such as the valves.

The workshop participants identified all of the above problem areas as important. They are listed in an approximate rank of priority. The first five areas were denoted as "most important" while the remaining areas were denoted "important."

10. WORKSHOP ON FIELD EFFECTIVENESS EVALUATION

The first conclusion of this group was the need to develop field tests for respirator effectiveness. Field tests are important because they can significantly improve respirator design, improve certification procedure by including field tests, permit both POI and POU testing of respirators, and permit better evaluation of respirator programs.

The workshop participants noted the preliminary results of workplace protection by NIOSH and recognized the rationale for "controlled" field testing by workers closely monitored for mask usage patterns. They recommended that methods be developed to test respirator protection during typical user condition, including training, maintenance, and workplace use. These methods should be used to study large groups of workers, enough to assess the effectiveness of respiratory protection programs.

Research needs were discussed and the group agreed that the following areas were important:

- Mask probe design
- Effect of probe location and flow rate
- Interaction of breathing cycle and deposition with sample concentration
- Effect of body and head movement on leakage
- Effect of work rate and work task on leakage

11. WORKSHOP ON NON-INTRUSIVE TEST METHODS

The workshop discussion began with an attempt to distill a set of objectives out of what had transpired in the general meeting. It was decided that our aim was to list criteria to be met by any methods and areas of research to pursue.

During the discussions, however, it was realized that the technology is not presently available that would allow immediate implementation of NIT. It seemed, rather that three stages were required: Stage I, where the measuring and recording system could be miniaturized enough to be carried by the subject but remain external to the mask; Stage II, that would find the sampling system small enough to be implanted in the mask; and Stage III, the entire system would be totally enclosed, and the recording signal would be telemetered out.

The criteria in the workshop would apply to Stage III, although at present we are just beginning to enter Stage I. As is obvious from the definition of NIT., given in the general discussion, the system must be totally enclosed in the mask and able to transmit a signal to some remote station. This necessitates minimal size and weight that will not affect the characteristics of the mask. The system must also be immune to or protected from mask cavity conditions of elevated temperature and high humidity. It must be fairly sensitive, able to measure low concentrations of challenge agent, while also being able to measure very high concentrations and clear quickly. In order to measure peaks of leakage associated with certain movements and differentiate between inhalation and exhalation, real time or delayed real time must be possible. Since the system would only be necessary during testing, and because it probably could not withstand the vigorous cleaning that the respirator would be subjected to, it should be a temporary unit, easily implanted and removed. Further, because there would be one unit mask, rapid

calibration and easy maintenance are required. And finally, there is the ever-present desire for nominal cost.

These criteria almost immediately remove present methods from consideration, although in the future present methods may be adapted to fit them. Some methods considered include chromatography, measurement of electrostatic charge, and light-scattering photometry. One problem encountered with the latter would be interference by water droplets in exhaled breath. (Perhaps this could be dealt with by using some hydrophobic coating on the sampler).

At this point, Stage III still seems fairly distant. In the meantime, the dynamic environment of the mask cavity needs extensive study, and any size dependence of leakage that exists must be determined. Further, innovative approaches to fit testing must be examined and bench-top experimentation of potential methods must be conducted. Finally, new sources of aerosols must be explored. In size dependence determination, laboratory methods of producing various size ranges must be developed to fill in present gaps. And in field testing, the feasibility of using naturally occurring aerosols must be analyzed; if this is found unsuitable, methods of large scale production of aerosols must be designed.

12. WORKSHOP ON GAS AND VAPOR TESTS

The workshop participants reached the consensus that a vapor method for respirator fit is necessary particularly for the military because the threat of principal concern is a condensable vapor. It is also believed that industry has similar concerns in many circumstances.

A vapor test method offers certain advantages over aerosol testing. For the military need to measure the equivalent of a "workplace protection factor" in the field, a simulant vapor is probably simpler to generate, control, and measure. The use of nontoxic vapors might also be used as a tracer to track workplace leakage in some industrial settings. Both active and passive systems are conceivable. Detection and Assay systems with great sensitivity are known. For example, hydrogen flame emission detection is an extremely sensitive method for sensing sulfur or phosphorus bearing vapors. For active systems miniaturized GC equipment already exists. A passive system might be as simple as adsorbent carbon pads inside and outside the mask. An extended system might employ time-sequenced exposure of the sorbent surface, thus providing a concentration history.

Passive systems could be "non-intrusive" by definition. The workshop listed the following as R & D needs:

- Acquire a data base on possible tracer materials-toxicity, physical and chemical properties
- Perform feasibility studies on possible methodologies, equipment and test procedures
- Develop prototype systems
- Perform comparative studies with prototype systems under controlled conditions with human subjects
- Develop correlations
  - Aerosol vapor
  - Between systems
- Develop final field-useable systems
- Acquire systems
- Design and conduct field trials

13. SUMMARY AND CONCLUSIONS

This peer group review meeting of respiratory QNFT methods was intended to consider:

- Advantages and disadvantages of presently used fit test methods
- Applicability of present methods to field effectiveness measurements
- Improved methods for determining leakage of respirators
- Other research needs to put the field of respiratory protection on a firmer scientific footing.

Both instrumentation and methodology were considered in presentations, discussions, and workshop sessions as important components of fit test measurement. An important concept enumerated early in the meeting was that fit tests serve several functions (research, evaluation, certification, POI, etc.) and

that the specific methods must apply to the appropriate need. Thus, new fit test methods and instruments must be designed for field effectiveness because present methods are only usable in the laboratory.

The development of fit tests methods from filter testing methodology involved several assumptions (maximum penetrating aerosol size) that are unproven for respirator leakage. There is a need to examine this issue, as well as a need to improve the dilution and calibration methods for both oil and salt at low aerosol concentrations.

Fundamental studies of leakage as a function of particle size are needed, with special attention to ultra-fine particles ($< 0.1\ \mu m$). The use of aerosol as a surrogate for vapor leakage needs to be critically examined and tested by simultaneous leakage measurements. Studies of the mixing of air within the cavity of full-face respirators are needed to elucidate the effect on leakage measurements and the role of design on rebreathing.

Once methods for field effectiveness measurements are developed, these should be applied to specific instances to obtain a data base for comparison of laboratory and field measurements. Initial studies suggest that present laboratory measurements may not be good predictors of field performance.

For POU testing (non-intrusive tests where mask integrity is maintained), accuracy, inexpensiveness and operational simplicity need to be developed. Several approaches appear to have potential for such measurements and should be investigated.

Both aerosol and vapor test methods for QNFT should be developed because there are certain situations where vapor agents are more desirable than aerosols. Feasibility studies of non-intrusive vapor methods should be supported as a possible field method. Specific suggestions for needed research are included.

14. RECOMMENDATIONS FOR FUTURE RESEARCH

Recommendations for future research, frequently with justification for the need, are given throughout this report and particularly in the sections dedicated to workshop deliberations. A summary of the major recommendations follows:

- With respect to currently used respirator fit test methods (NaCl, Oil Aerosol)

  - Develop dilution and calibration techniques suitable to 100,000 X and permit independent verification.

  - Determine suitability of these or other aerosols as surrogate for vapors. Correlate aerosol data with vapor data, preferably simultaneously acquired.

  - Determine effect of particle size and other particle parameters (e.g., charge, physical state, etc.) upon respirator penetration (include particles > 0.1 μm and > 5 μm).

  - Develop method for measuring size distributions inside and outside a respirator.

  - Complete toxicological data base for oil to be used as test aerosol.

  - Develop upgraded instrumentation to include:

    - automated sampling
    - automated data analysis
    - higher sensitivity detectors (for Fit Factor 10^5 - 10^6)

- With respect to new respirator fit test methods:

  - Conduct research leading to development of nonintrusive test methods for field test use. In view of current limitations in the state of the art in applicable technology, consider a phase approach.

Stage I: Measuring and recording system, miniaturized but carried by subject external to mask.

Stage II: Sampling system small enough to be implanted in mask.

Stage III: Entire system enclosed in mask with signal telemetered.

Approaches with potential leading toward Stage III are listed in this report. Priority emphasis should be given to laser light scattering photometry and miniaturized chromatography.

  - Develop a vapor test method especially for military field test use. Consider both active (e.g. miniaturized GC) and passive (e.g. adsorbent pads inside mask) approaches.

  - Investigate feasibility of using naturally occurring aerosols for field testing.

- Additional research needs applicable to all methods

  - Effect of probe design, location and flow rate on leakage data

  - Interaction of breathing cycle and deposition with sample concentration

  - Effect of work rate, work task, body and head movement on leakage

  - Define psychological factors that influence operator usage

- Obtain agreement of the technical community with respect to:

  - Terminology and definitions for respirator fit test and results

  - Standardization of fit test apparatus and procedures

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1. Pritchard, J.A., A Guide to Industrial Respiratory Protection, HEW Publication No. (NIOSH) 76-179, Supt. Doc., USGPO, Washington, DC (1976).

2. Myers, W.R., et al., Letter to the Editor, AIHAJ, Vol. 44, p B-26 (1983).

3. Caldwell, R., and Schnell, E., Respirator Effectiveness in an Enriched Uranium Plant, Presented at the 1968 American Industrial Hygiene Conference, St. Louis, MO.

4. Willeke, K., Ayer, H., and Blanchard, J., "New Methods for Quantitative Respirator Fit Testing with Aerosols," AIHAJ, Vol. 42, pp 121-125 (1981).

5. Wallendorf, L.J., "A Comparison of Dioctyl Phthalate and Sodium Chloride for Respirator Fit Testing," M.H.S. Essay, John Hopkins University School of Hygiene and Public Health, Baltimore, MD 21205 (1980).

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8. Binley, R., Notes from a Seminar on Resp. Prot., JHU SHPH (1982).

9. Samimi, B., et al., "The Efficiency of Protecitve Hoods Used by Sandblasters to Reduce Silica Exposure," AIHAJ, pp 140-148 (February 1975).

10. Levine, M.S., "Respirator Use and Protection from Carbon Monoxide," AIHAJ, Vol. 40, p 832 (1979).

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APPENDIX A

MEMBERS OF THE PEER REVIEW GROUP

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Name
John A. Pritchard
Warren R. Myers
Ching-tsen Bien
John McCreadie
John C. Boardway
Jugal K. Agarwal
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Frank Rosenthal
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Samuel J. Troutman
James J. McCrystal
Klaus Willeke
Richard W., Brletich
Tom Hall
Frank Shanty
David L. Swift
Charles E. Billings

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APPENDIX B

PROGRAM AGENDA AND SCHEDULE

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SCIENTIFIC PEER GROUP REVIEW OF RESPIRATOR QUANTITATIVE FIT TEST METHODS

Time: Thursday and Friday, March 24 and 25, 1983

Place: The Johns Hopkins School of Hygiene and Public Health

AGENDA

Day 1

8:30 am - 9:00 am	Introduction and Objective of Peer Group Review Meeting; Workshop Assignment	C. Billings
9:00 am - 9:45 am	Summary Review of Aerosol and Gas/Vapor Respirator Fit Test Methods and Equipment, Criteria for Non-Intrusive Test Methods	D. Swift
9:45 am - 10:15 am	Break	
10:15 am - 10:40 am	DEHP/DEHS (Corn oil) Liquid Aerosol Particle Apparatus and Procedures: Experience, Advantages, Disadvantages, and Areas of Additional Research Needed	H. Ettinger
10:45 am -11:15 am	NaCl Solid Aerosol Particle Apparatus and Procedures: Experience, Advantages, Disadvantages, and Areas of Additional Research Needed	J. McCreadie
11:15 am - 11:40 am	Review of Field Tests of In-mask Exposures in Industrial Environments	W. Myers
11:40 am - 12:00 n	Gas/Vapor Tests and Suitability of Aerosol Particulate Tests as Surrogate for Fit for Gas/Vapor Exposures	C. Billings

12:00 n - 1:30 pm	Lunch	
1:30 - 2:30 pm	Discussion of Non-Intrusive Test Apparatus and Procedures and Potential New Test Apparatus and Procedures, (List, Discuss, Prioritize).	D. Fay
2:30 - 2:45 pm	Criteria for Tests vs. Objectives vs. Location	C. E. Billings
2:45 - 3:00 pm	Break	
3:00 - 5:00 pm	Workshops on Needed Research Requirements: A. Improvements to Current Methods, Apparatus and Procedures B. New Methods for Laboratory or Point-Of-Issue Fit Tests C. Design of Methods for Field Evaluation of Respirator Effectiveness During Use D. Non-Intrusive Fit Test Apparatus E. Gas and Vapor Fit Test Apparatus and Procedures	
5:15 - 6:15 pm	Wine and Cheese Mixer on 9th Floor Cafeteria	

Day 2

8:30 - 10:00 am	Workshops on Needed Research (continued)	
10:00-10:30 am	Break	
10:30 - 12:00 n	Review and Reports	
12:00 n	Laboratory Walk Through. (Lunch in cafeteria if you wish)	

SCIENTIFIC PEER GROUP REVIEW OF RESPIRATOR QUANTITATIVE FIT TEST METHODS

Workshop Group Assignment			Room
A.	Current Methods	H. Ettinger, Leader J. Pritchard J. Agarwal T. Boardway F. Rosenthal, Rep.	2006
B.	New Laboratory Methods	R. da Roza, Leader J. DeField S. Troutman G. Sem D. Swift, Rep.	2008
C.	Field Evaluation Effectiveness	W. Myers, Leader R. Laird C. Bien V. Bergman C. Billings, Rep.	2010
D.	Non-Intrusive Test Methods	K. Willecke, Leader J. McCreadie W. Burgess C. Shoemaker D. Fay, Rep.	2033
E.	Gas-Vapor Tests	B. Gerber, Leader P. Breysse D. Campbell J. McCrystal F. Shanty, Rep.	Board Rm

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APPENDIX C

H. ETTINGER VISUAL AIDS

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Oil QNFT

1) Technique Highlights.

2) Advantages

3) Limitations, Problems, Uncertainties
   a) Oil
   b) General

Oil Aerosol

CMD ~ 0.2 - 0.4 μm

MMD ~ 0.4 - 0.9 μm*

σ_g ~ 1.3 - 2.0

C ~ 1 - 4 mg/m^3

* One investigator high

POTENTIAL MATERIALS

DEHP (DOP)
DEHS (DOS)
Corn Oil
Mineral
Soybean
Peanut
Cottonseed
Salad
Olive
Oleic Acid

Oil System Charact.

Sampler Flow - 1-5 lpm

Fit Factor Definition

≤ 10,000 - 20,000

Cost

$ 5 - 10^K

Advantages

1) Simple Aerosol Generation
2) Relatively Reproducible Aerosol
3) Alternate Oils Acceptable
4) Appropriate Size Range
5) Liquid Aerosol Minimizes Loading
6) Particulate Simplifies Test
7) Instrumentation Measures F.F. Up to 10,000
8) New Instrumentation Should Measure FF Up to 100,000
9) Non-Intrusive Sampling Seems Practical

LIMITATIONS, UNCERTAINTIES (GENERAL)

1) Standard Methodology

2) Importance of Particle Size

3) Response to Aerosol Size within & Outside Mask

4) Critical Sampler Location within Mask

5) Relationship between:
   a) Fit Factor (PDI)
   b) Protection Factor
   c) Field Protection Factor (PDL)
   d) Worker Use Factor
   e) Q.L.F.T.

6) Standard Definitions of Terms in (5)

LIMITATIONS, UNCERTAINTIES (OIL)

1) Toxicology of Oils
2) Consistency of Materials
3) Photometer Linearity
4) Oil Bacterial Growth.
5) High F. F; Instrumentation & Technique Proofing
6) Non Invasive Sampling; Instrument. & Technique Proofing

LIMITATIONS, UNCERTAINTIES (GENERAL)

7) Standard Exercise Simulation

8) Perspective of Fit Factor vrs. Worker Use Factor (WUF)

9) Interpretation of Probability of Safety Provided

$$WUF = \frac{FF}{(FF)\left(\begin{matrix}\text{Time}\\ \text{Not}\\ \text{Worn}\end{matrix}\right) + \left(\begin{matrix}\text{Time}\\ \text{Worn}\end{matrix}\right)}$$

If $FF \geq 100$

$$WUF \approx \frac{1}{\text{Time Not Worn (Fraction)}}$$

	Time Not Worn (Fraction)				
FF	0.8	0.5	0.2	0.1	0
10	1.2	1.8	3.6	5.2	10
100	1.2	2.0	4.8	9.2	100
1000	1.3	2.0	5.0	10.0	1000

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APPENDIX D

METHOD OF DATA ANALYSIS FOR OIL PARTICLE PENETRATION ESTIMATE

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RESULTS

Test aerosol facepiece penetration measurements during each inspiration-expiration cycle were recorded, as illustrated, in Figure 8, A Typical Test Penetration Record. The average peak penetration was calculated in the following manner. In the particular strip chart record shown, there were 12 inspirations recorded during the first 1-min exercise, normal breathing. Peak penetrations at maximum inspiration were estimated at the end of each breathing cycle: 64, 63, 84, 61, 55, 72, 70, 56, 89, 61, 49, and 42% respectively. The average of these 12 values was then calculated (63.3%). These estimations and averages were recorded for each exercise mode. Finally, the overall average of these six modal averages, 63.3, 39.4, 28.4, 42.1, 38.6, and 52.7%, was calculated (44.1%).

$$Pen = 44.1\ \% = 0.441,\ PF = 1/.44 \sim 2$$

The procedures were repeated for each of the three tests. The overall average peak penetration (%) for each test may be found in Appendix A. A Friedman two-way analysis of variance of this data was done by computer. A portion of the original print-out may be found in Appendix II.

The average peak penetration for each respirator by test subject was calculated for the three test runs. The computed average and range of peak penetrations (%) is recorded in Table 1.

Formally, the average penetration for each respirator and test subject was calculated from:

$$\text{Average Penetration} = 1/3 \sum_{k=1}^{3} 1/6 \sum_{j=1}^{6} 1/n \sum_{i=1}^{n} p_{ijk}$$

where: i = number of inspirations per exercise mode
j = number of exercise modes per test
k = number of tests (repetitions)
p = maximum penetration recorded in a single inspiration (%)

Figures 9 and 10 graphically compare the average peak penetrations (%) of the two aerosols by respirator and test subject, respectively.

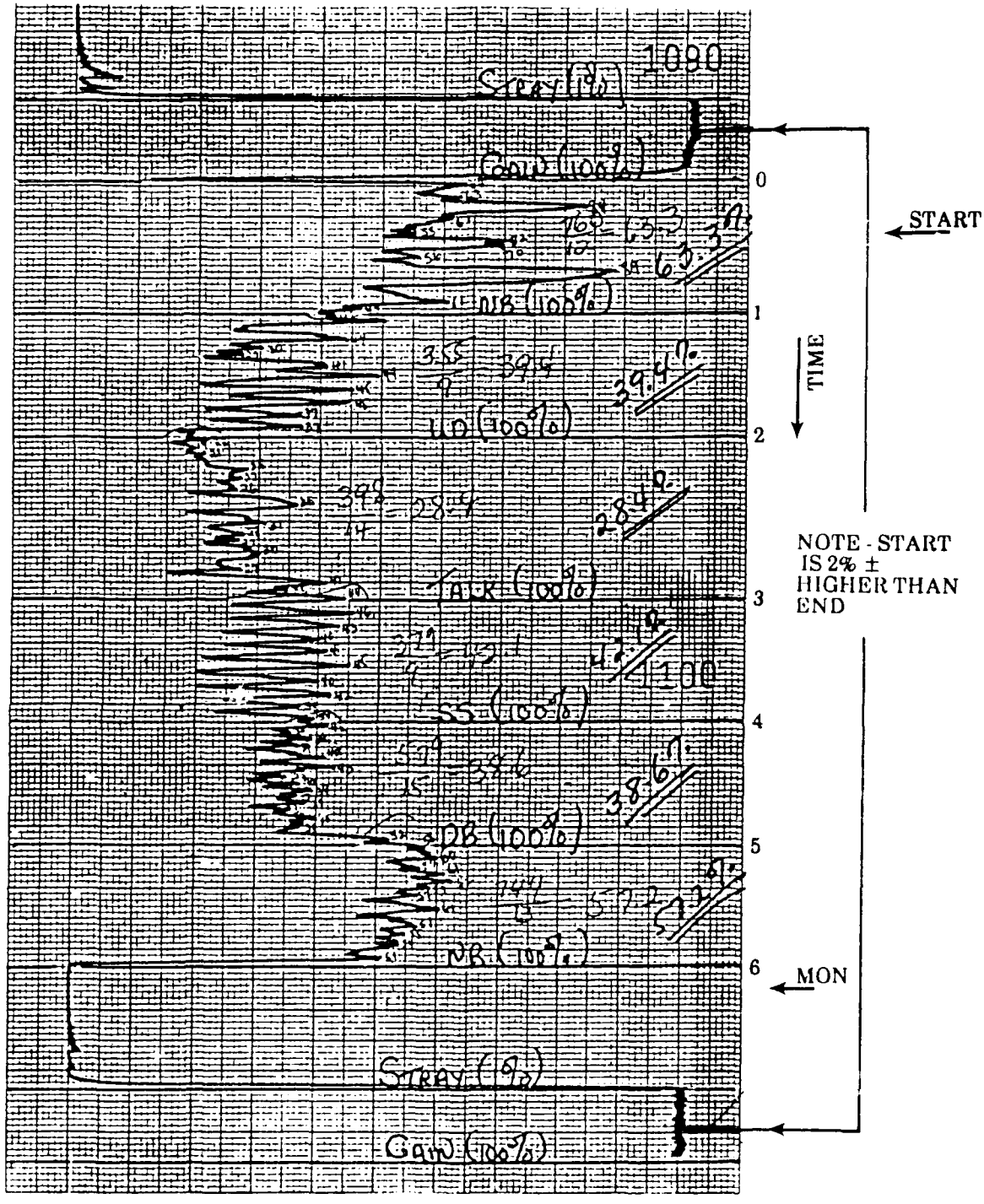

Figure 8. A Typical Test Penetration Record.

APPENDIX E

NATIONAL DRAEGER MASK FIT TESTER

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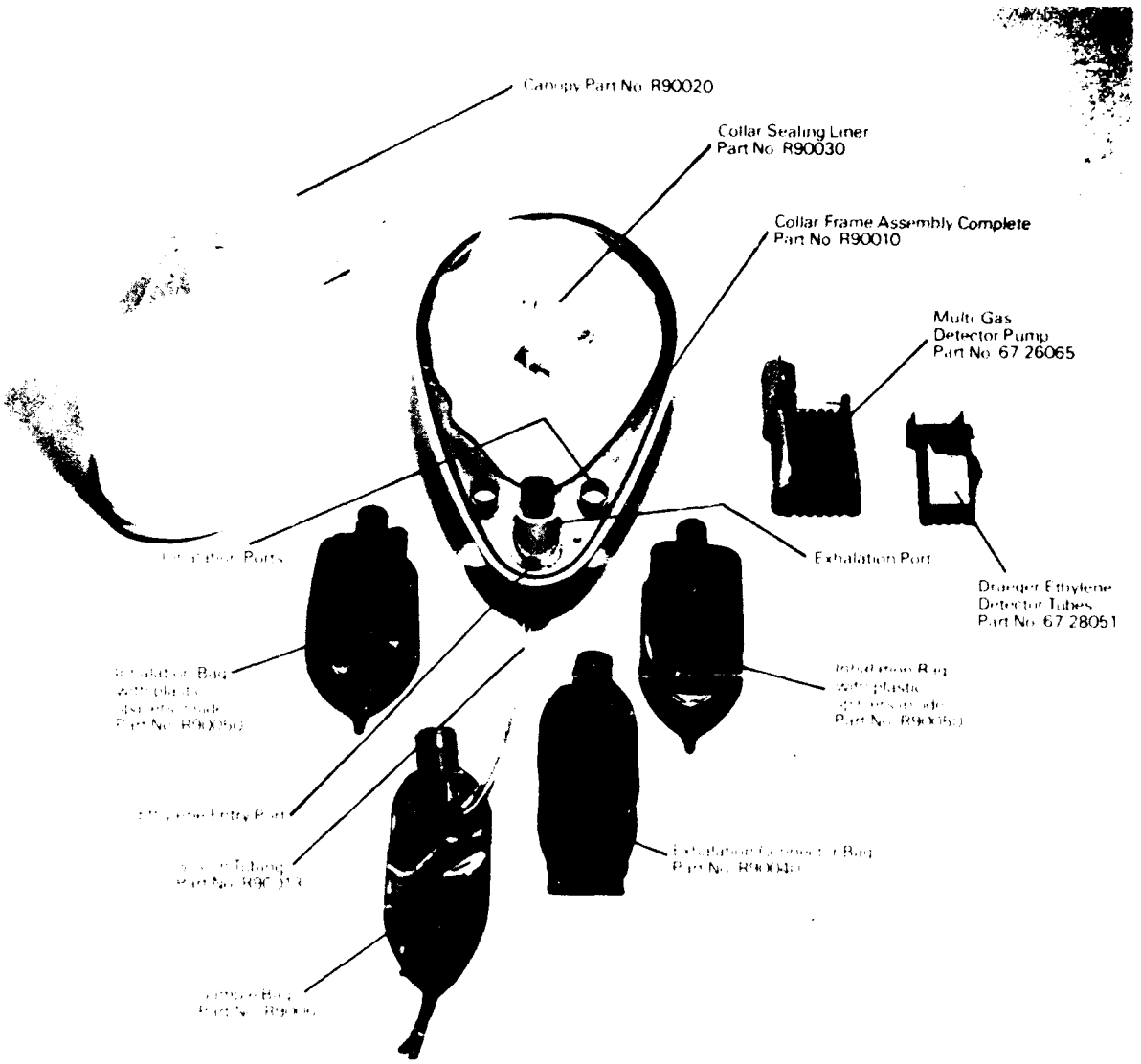
National Draeger

Canopy-Type Mask-Fit Tester

PARTS LIST



Ordering Information:
Specify Draeger No. R9000

Figure 1. Parts List for National Draeger Canopy - Type Mask Fit Tester.

MASK-FIT TESTER
National Draeger, Inc.

101 Technology Drive Pittsburgh PA 15275 412 787 8383
TELEX 86-6704

Subject:

Canopy-Type Unit for Half-Mask Fit Testing

This National Draeger system allows, *quantitative* measurements to be made of mask fit — reliably and very economically.

The testing system is based on using ethylene gas as a means of evaluating breathing mask tightness — reading the amount of ethylene gas in exhaled air with a Draeger Gas Detector Tube.

The National Draeger Canopy-Type Test Hood is applied to the subject wearing a half-mask respirator. With ethylene gas admitted to the Test Hood, the subject breathes normally. A Draeger Ethylene Detector Tube and Multi-Gas Detector Pump are used to read the amount of ethylene in exhaled breath — providing a *quantitative* measurement of the mask leakage.

Collar in position with Collar Liner forming a seal at the neck of subject

Half-Mask in position with two inhalation bags and exhalation chamber leading to test bag applied in ports in Collar.

Applying Canopy into which ethylene is fed — prior to beginning of fitness test.

Figure 2. Canopy-Type Unit for Half-Mask Fit Testing

APPENDIX F

NON-INTRUSIVE TEST METHODS

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PAPER STUDY OF NON-INTRUSIVE QNFT METHODS

1. INTRODUCTION AND DEFINITIONS

Respirator QNFT can be employed for several purposes, as emphasized above in the Peer Review Report. These include research and development of respirators, certification, POI, POU, re-test after use, and re-test after storage. Presently used methods, as discussed below, have been designed primarily as a special type of initial POI testing where the wearer determines what size respirator gives the best fit and tests the donning and adjustment of the respirator to give an "acceptably minimal" degree of leakage.

In such tests, the user is not tested with their own respirator, but with a standard size respirator that has been fitted for QNFT. From discussion and data presented at the Peer Review Meeting, it appears that such "laboratory" tests, while fulfilling the requirement of finding an "optimal fit" do not assure that the degree of protection measured in such tests will be realized in the field use of the respirators.

This argument is the rationale for developing new methods of QNFT that can be used in the field and can be carried out on the wearer using their own respirator. It is a requirement of such tests that the respirator be fit for use after the test. Most existing QNFT methods (except as discussed below) first require the respirator cavity be sampled through a tube that penetrates the mask somewhere on the facepiece. We define such test methods as 'intrusive' both because they require penetration of the mask, thus compromising its integrity, and because the sampling intrudes upon the normal movement of air within the mask during inspiratory and expiratory movements. The effect of sampling air for concentration measurement is not known, but it may produce an altered pressure distribution compared to the normal situation without sampling. Conversely, a QNFT method that does not require the integrity of the mask to be compromised and that measures concentration without extracting air from the mask is defined as a non-intrusive QNFT.

It is the purpose of this section to review existing tests that are non-intrusive, to consider criteria that a new non-intrusive test must meet, to list possible methods that might be employed for such tests, and to suggest what methods appear to be most feasible and worthy of research investigation and development.

2. PRESENT NON-INTRUSIVE METHODS

A survey of methods that are being or have been used for QNFT indicates that two gas methods and one aerosol method could be classified as non-intrusive. These will be described briefly below and critically evaluated in general and specifically for field use.

Argon gas has been used (1) to test the leakage of full face masks. In this test, the head and upper body are enclosed by a plastic hood that is cinched about the waist. Pure argon gas is injected into this space from an inlet tube atop the head and bathes the region about the respirator. The respirator inlet and outlet valves are connected to flexible tubes. Oxygen is fed through these tubes to the mask (by a demand regulator) and expired air is vented to the outside via a sampling bladder. From this bladder a sample is taken for gas analysis with a mass spectrometer whose sensitivity is stated to be of order 10 ppm. Thus, with pure argon outside the mask, a concentration ratio of up to 10^5 is, in principle, possible to measure. The subject was able to do a limited number of simple head movements and walk on a treadmill during the test. However, the subject had to remain tethered to the argon supply and to the sampling bladder during the test.

As a laboratory method to test respirator leakage, this method exhibits good sensitivity and employs a proven analytical method, mass spectrometry. However, its disadvantages include the use of inspiratory and expiratory tubes that may limit head movement and distort the mask fit because of their weight. Sampling exhaled air to estimate mask leakage has been favored by some investigators. This approach requires that respiratory uptake be known, that mixing between tidal air and mask space air be estimated, and that no backmixing occur in the exhalate line. For argon, the first factor is known, but the other factors are uncertain, as is the concentration of argon around the mask assumed to be 100%.

As a field method, this method does not seem feasible since it requires a gas tank and a mass spectrometer, an instrument that at present, is not manufactured for use in the field. It also does not permit body or head movement that would simulate the job activity of respirator users.

A somewhat similar gas method is the ethylene leakage test that was developed by National Draeger and is described in detail in Appendix E of the Report. It differs from the argon

test in that breathing tubes are not used and the exhaled air concentration is sampled by a color indicating tube.

In this method, the bag covering the head has appropriately placed holes to fit over the inhalation cartridges so the subject can breathe air without tube connections while the remainder of the mask and head are bathed in air containing 2% ethylene. An exhalation line leading to a sampling bladder leaves the bag through a tight fitting hole.

A detector tube for ethylene has a detection limit of approximately 1 ppm; thus a leakage factor (PF) up to 2×10^4 can be measured with an accuracy of approximately 25% (that of the detector tube). A source of 2% ethylene (a calibrated tank) must be available to conduct this leakage test, making the method difficult to perform in a field situation. Similar questions regarding the free movement of head and body (as with argon test) apply to the ethylene test. Ethylene is not significantly removed in the respiratory tract, but the relationship of mask concentration to exhaled air concentration is not known in general.

The only aerosol method that could be considered non-intrusive is the method employing airborne bacillus subtilis or bacillus globigii. In this method, a water suspension of the bacterial organisms is nebulized into a chamber and monitored by a light scattering photometer to maintain a reported concentration of about 300,000 organisms/L air. The subject wearing the respirator remains in the chamber for a specified period; any airborne organisms entering the mask cavity and reaching the mouth are collected on a cotton plug filter held in the mouth in a brass fitting. The number of organisms deposited on the cotton filter is determined by standard microbiological colony counting following incubation. The particles are reported to have an aerodynamic mass median diameter (MMD) of about 1.0 m. Because it is possible to detect a single organism, this method theoretically allows one to measure protection factors in excess of 10^6 for an exposure period of several minutes.

Despite this high protection factor detectability, the method has not been widely used for leakage measurement. Although the organism is not pathological, it does represent some risk if individuals of unusual susceptibility come into contact with the live organism. Furthermore, it requires some care to culture and maintain the organisms in a state where they can be conveniently used for aerosolization. For these reasons it does

not appear that the E.G. method would satisfy the criteria of dose and portability for a fieldable non-intrusive method.

A review of existing gas and aerosol non-intrusive methods suggests that none are suited for field leakage measurements that can give the desired sensitivity, portability, and ease of operation. This conclusion suggests that new methods of non-intrusive leakage measurements should be developed. From a number of possible methods that might be used, several promising methods should be chosen and extensive research and development performed. Of first importance in narrowing the field of methods is the establishment of criteria for a field use non-intrusive QNFT.

3. CRITERIA FOR NON-INTRUSIVE QNFT

Ten primary criteria were chosen for field use non-intrusive QNFT. It is believed that if a method best meets these criteria, it will be the most ideal way to test leakage for a respirator. These criteria are listed in Table I with a short comment or explanation.

Table I. Criteria for Non-Intrusive QNFT.

1.	Portability - can be easily carried to a field location
2.	Ease of Performance - not requiring a technically trained operator
3.	Sensitivity - able to measure leakage factors > 100.000
4.	Specificity - not interfered with by other contaminants
5.	Accuracy - gives a "True" measure of leakage
6.	Precision - reproducibility greater than intra-subject variability
7.	Non-intruding - permits normal working conditions or desired movements
8.	Mass Producible - can meet engineering specifications for manufacturing

Table I. (continued)

9.	Safe - presents no hazard to wearer or tester
10.	Inexpensive - does not add significantly to cost of respirator

The methods that were considered for development were also judged with respect to four other issues listed in Table II. Existing methods fall into both "real time" and "integrated" categories. The flame photometry and forward light scattering methods are both "real time" in that "instantaneous" concentrations of aerosol are recorded during breathing maneuvers to show those movements that are responsible for highest leakage. Conversely, the B.G. method gives a single leakage value for the entire period of exposure that is an integrated time averaged value. For this method, specific movements or exercises cannot be associated with a leakage factor.

Table II.

Additional Factors Influencing QNFT Methods
Integrated vs. Real Time Cavity Concentration Detection
Interior vs. Exterior to Mask Cavity Detection Device
Temporary vs. Permanently mounted Air Sample Removal vs. Detection without Sampling

Real time detection of leakage has been considered more desirable than integrated, but it may not be possible to meet all other criteria successfully and have a continuous concentration monitor as well.

The location of the detection device is also an important issue. Present methods of gas and non-viable aerosol exposure all employ exterior detection with air sampling. A detector within the mask cavity would be more desirable, but it must not interfere with normal mask function. Exterior detection might be done without air sampling, such as by light scattering through the mask eye lenses.

The type of detector employed is the primary determinant with respect to whether the detector is temporarily or permanently mounted. For retest, it is desirable to have a permanent detector, but it might not be possible to maintain the detection capability over a period of time. The effect of sampling air from the mask cavity is not known, but it is probably more desirable not to sample air from the cavity by pumping, even if this can be done consistent with continued mask use.

4. METHODS CONSIDERED

A number of methods for non-intrusive QNFT were considered and judged as to the criteria. These fall into three categories:

- Modifications to existing sampling techniques
- Physical and chemical detection methods
- Biological assay methods. (These methods are summarized in Table III.)

Table III.

Non-Intrusive QNFT Methods

Modifications	Chemical, Physical Detection	Bioassay
Permanent "Leak-Proof" Value	Colorometric Paper	Urinalysis
	Passive Dosimeter	Blood Analysis
	Visible Light Scattering	Ear Lobe Monitor
	IR, UV Spectroscopy	Skin Conductance
	Magnetic Detection	Skin Visual Analysis
	Gas Chromatography	Dye on eye sclera
		Exhaled air analysis
	Radioactive gas or aerosol	
	Direct Exhalate Analysis	
	Solid state gas detector	
	Ionization aerosol detector	
	Condensation Nuclei Center (CNC)	

Consideration was first given to the bioassay methods taken as a whole. While these are attractive because they permit measurement of actual "dose", they are generally invasive to a degree that makes the procedures difficult to administer on a large scale. Therefore, the conclusion was reached that these methods were not feasible. The permanent valve option is the simplest approach because it permits existing detection methods such as flame photometry and light scattering to be used. However, it is not truly "non-intrusive" in that it cannot be assured that the valve will be "leakproof." While this approach could be taken, it is our opinion that it is not the best approach and should be considered a back-up if other approaches do not give desired results in development.

Among the category of chemical or physical detection methods, several approaches do not appear at present to have promise of success in meeting all criteria. Magnetic detection does not have required sensitivity, while radioactive gas or aerosol is unacceptable from a subject exposure viewpoint. The first two methods are simple but do not offer real time analysis. If this criterion is not necessary they should be developed. While CNC detection is sensitive, it is not non-intrusive, requiring a sample to be drawn from the cavity. The most attractive methods appear to be solid state gas detection, ionization aerosol detection, and gas chromotography. Devices employing these principles of detection and analysis have been proposed and would fit comfortably within the mask cavity. However, at present such devices are not commercially available that have the desired degree of sensitivity and selectivity. It appears that further development to perfect such detection devices will be required to achieve a field effective non-intrusive QNFT.

5. CONCLUSIONS

- There is a need for development of a non-intrusive, field effective QNFT method that can achieve leakage measurement equivalent to fit factors > 100,000.

- No present methods of QNFT are capable of modification to meet the criteria for a field effective non-intrusive QNFT.

- Of the possible methods considered, taking into account developed criteria, methods that have most

promise are aerosol ionization detection, solid state gas detection, and gas chromatography, all being capable of miniaturization to fit within a mask cavity.

- Applied research and development is needed in order to achieve the goal of a fieldable non-intrusive QNFT and should be undertaken in the above areas.

APPENDIX G

DEVELOPMENT AND ASSEMBLY OF VAPOR/AEROSOL TEST

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DEVELOPMENT AND EXPERIMENTAL ASSEMBLY OF A SYSTEM FOR SIMULTANEOUS VAPOR/AEROSOL LEAKAGE MEASUREMENT IN A FULL FACE RESPIRATOR

1. INTRODUCTION

Although several leakage tests employ gases or vapors as test agents, the commonly used QNFT methods employ either NaCl or oil aerosol. The standard U.S. Army mask is intended for protection against both aerosol and vapor agents, employing a filter and a treated charcoal bed. If these elements are equally efficient in removing agents in the inspired air, leakage into the mask cavity is likely to occur primarily around the faceseal. Since vapor agents, such as Savin (GB), are a major concern in the employment of masks, it is important to know if protection against aerosol is predictive of protection against vapor. Simply stated if a fit factor is measured using aerosol QNFT, the same degree of protection can be assumed for vapor.

Several studies have been carried out where respirator leakage was measured first with an aerosol and then with a vapor surrogate agent. In all cases, the measurements were done sequentially, and it is possible that changes in leakage occurred between measurements. In order to avoid this difficulty, we proposed to develop a fit test system that made simultaneous aerosol and vapor leakage factors and tested the hypothesis that facepiece leakage of test aerosols is equivalent to vapor leakage of a nerve agent surrogate.

2. CHOICE OF AGENT-AEROSOL

Of the two common aerosol substances, NaCl and oil, it was necessary first to choose a specific aerosol agent for the test system. There are several oil agents that have been employed including DOP (properly di-2-ethyl-hexyl phthalate DEHP), DEHS (Sebacate), corn oil, and PEG (polyethylene glycol). If oil is to be used rather than NaCl, a specific oil must be chosen.

The primary advantages of oil over NaCl are the non-hygroscopic nature of oil droplets, the ease of generation by air nebulization, and its constant output characteristics. Another advantage is the light scattering method for oil aerosol concentration measurement; it is less likely to suffer vapor interferences than the NaCl flame photometry technique.

Several studies have shown that the particle size of oil aerosol produced from a Laskin nebulizer is similar for DEHP, DEHS, PEG, and corn oil. Because of this similarity and the experience in our laboratory with DEHS, we chose this oil as the aerosol agent. Furthermore, an Inhalation Toxicology Study has been carried out with DEHS on Fisher rats and the study failed to show significant lung or systemic effects at exposure levels up to 250 mg/m^3 for exposure periods up to 13 wks. Likewise, DEHS aerosol exposures of a selected number of human subjects for deposition measurements have not demonstrated acute or chronic health effects.

3. CHOICE OF AGENT - VAPOR

The purpose of this phase was to select a surrogate that is a suitable substitute for a vapor organophosphate chemical warfare agent. Of such agents, the substance chosen to simulate was sarin (GB). The first task was to decide upon the physical parameters that should be the basis for a choice of surrogate. It was decided, based on factors affecting leakage through a facepiece seal, to seek substitutes that had similar vapor pressure and water solubility. Additionally, the substitute must have low toxicity, be detectable by a well established analytical method, and not be excessively expensive to purchase. Table 1 is a list of 30 compounds that were originally selected for consideration. After careful screening, all but two were rejected on one or another basis; the remaining compounds were isobutyric acid and dimethyl methyl phosphonate (a surrogate for organophosphate agents used by the U.S. Army for decontamination and adsorption breakthrough studies). Isobutyric acid was rejected because of its odorant property. Table 2 is a comparison of di-methyl methyl phosphonate (DMMP) and GB. Even though the vapor pressure at room temperature is less than that for GB, DMMP has sufficient volatility to achieve an airborne concentration in excess of 600 ppm, and has high water solubility similar to GB. DMMP is readily available in relatively pure form and can be generated easily by bubbling dry air through the bulk liquid. It is sufficiently non-toxic to be used for QNFT for a period of several minutes.

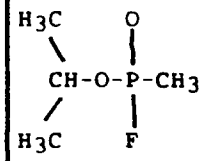
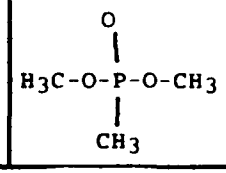
Table 1. Compounds Considered as Simulants for GB and Reasons for Rejection.

Compound	Vapor Pressure	Toxicity	Solubility	Detectability	Availability	Other
Trimethyl phosphate	X					
Triethyl phosphate	X					
Tribromomethane	X					
1-Bromo-2-butanol					X	
2-Hexanoi				X	X	
Trans-fumaryl chloride	X					
Z-methyl propionyl bromide					X	
1,3-dibromo-2-methyl-propane					X	
Isobutyric Acid						A
Ethyl glycolate					X	
2-chloropyridine	X					
Amyl alcohol				X		
2-chlorophenol				X		
Di-(2-methoxy-ethyl)ether					X	
Enanthaldehyde					X	
2,2,4-Trimethyl-3 pentanone					X	
1,2,4-Trimethyl-benzene			X			
Isoamyl isobutyrate					X	
Isobutyl benzene			X			
Dipentene			X			
d-Limonene			X			
Myrcene			X			
Cineol				X		
1-Decene				X		
Sulfur hexa-fluoride						B
Freons (all)	X					

A - unpleasant odor

B - not excluded by mask or cartridge

Table 2. Comparison of GB and DMMP, the Compound Selected as a Nerve Gas Simulant.

Compound	Structure	MW	Vapor Pressure	Volatility	Solubility	Experimental Inhalation Toxicity*
G B		140.1	1 mm Hg @ 13.53 °C 2.2 mm Hg @ 25 °C	16,800 mg/m^3 @ 25 °C	H_2O	LC_{50} = 100
DMMP		124	0.61 mm Hg @ 25 °C	4074 mg/m^3 @ 25 °C	H_2O	LC_{50} = 1.2 X 10^6

*Expressed as (mg/m^3) - minutes, for rats.

4. EXPERIMENTAL SETUP

Having chosen the aerosol and vapor agents, we proceeded to assemble elements of a leak test system for measurement of aerosol and vapor mask penetration. These elements consisted of agent generation apparatus, an exposure chamber, sampling system for aerosol and vapor, and analyzers to measure agent concentration in the box and within the mask cavity.

Aerosol generation was accomplished with a Laskin nozzle nebulizer, commercially produced by Air Techniques, Baltimore, MD (Model TDA-4A). This produces a polydisperse DEHS aerosol having a MMD of 0.9 μm and output mass concentration of 4 mg/L. Using one nozzle for generation, we measured a flow rate of 15 L/min from the generator. This flow was diluted with filtered room air up to 50 L/min to feed to the exposure box. Calculated chamber concentration is approximately 1000 mg/m^3 (1 mg/L).

Initially, the DMMP vapor was generated by Ultrasonic nebulization of liquid from a DeVilbiss Model 35 Ultrasonic Nebulizer. However, this device uses a plastic cup to contain the liquid, and this was found to be unacceptable because of chemical interaction with DMMP. It was decided that generation should be carried out in a glass apparatus. For this purpose we employed a simple gas bubbler containing 100 mL of liquid DMMP with a fritted glass bubbler beneath the liquid to assure adequate air-liquid contact.

The DMMP vapor, at a concentration of 100 ppm (500 mg/m^3) was conducted to the chamber by a heated flexible plastic hose of 1-in. diameter at a flow rate of 50 L/min. The vapor and aerosol lines entered the chamber at the top through separate ports located about 3 in. apart.

The chamber was a modified shower stall, purchased from Air Techniques, Model TDA-70. It is large enough for a single subject to stand upright and carry out simple head and arm movements. Aerosol and vapor, with diluting air totaling 100 L/min, entered the top of the chamber and was mixed by a small propeller fan in the upper corner. Air left the chamber through a bottom drain and was pumped to the exhaust by a small centrifugal blower. Pressure inside the chamber was maintained at about 0.1" H20 negative.

The sampling ports for chamber and mask concentration were located about waist high at the side of the chamber. The chamber sample port extends 1 to 2 in. into the chamber while the mask port had a cone fitting for a 1-mm diameter Tygon tubing extending from mask facepiece to port. Slack was left to permit head movement.

Aerosol analysis was carried out with a forward light scattering photometer. This device contained an optical chamber obtained from Dynatech Frontier (Albuquerque, NM) that included a light source and photomultiplier. Electronics and gas handling in the photometer were constructed according to a design kindly supplied to us by Alan Hack of Los Alamos National Laboratory.

DMMP analysis was performed in a CSI Meloy Model 260 HYFED Phosphorus Analyzer. This instrument is stated to have a sensitivity of 0.0001 ppm phosphorus. In the original design of the system, the chamber sample was split into two streams. One stream was for the DEHS measurement in the photometer and the other stream was for DMMP measurement. Because of saturation problems in the HYFED at 100 ppm DMMP, we intended to run the sample through a dilution system to reduce its concentration by a factor of 625; however, this system itself was difficult to operate without saturation occurring in the rotameters and we concluded that this system should not be used in the final configuration. It is intended, presently, to measure only the mask concentration with the HYFED and measure the chamber concentration by infrared transmission (MIRAN Gas Analyzer). Figures 1-4 are diagrams of the flow configurations of aerosol and vapor generation, sampling, and analysis in the original configuration.

5. CALIBRATION

The photometer was calibrated with DEHS aerosol contained in a 100-L chamber whose original mass concentration was determined gravimetrically by sampling onto a membrane filter. Dilution of the aerosol was carried out in stages by removing 90% of the air in the chamber and replacing the filtered air. From this procedure, we obtained a series of calibration points shown in Figure 5.

The HYFED analyzer was calibrated using a DMMP permeation tube flow at CRDEC (Edgewood, MD). The calibration curve for this instrument is shown in Figures 6 and 7.

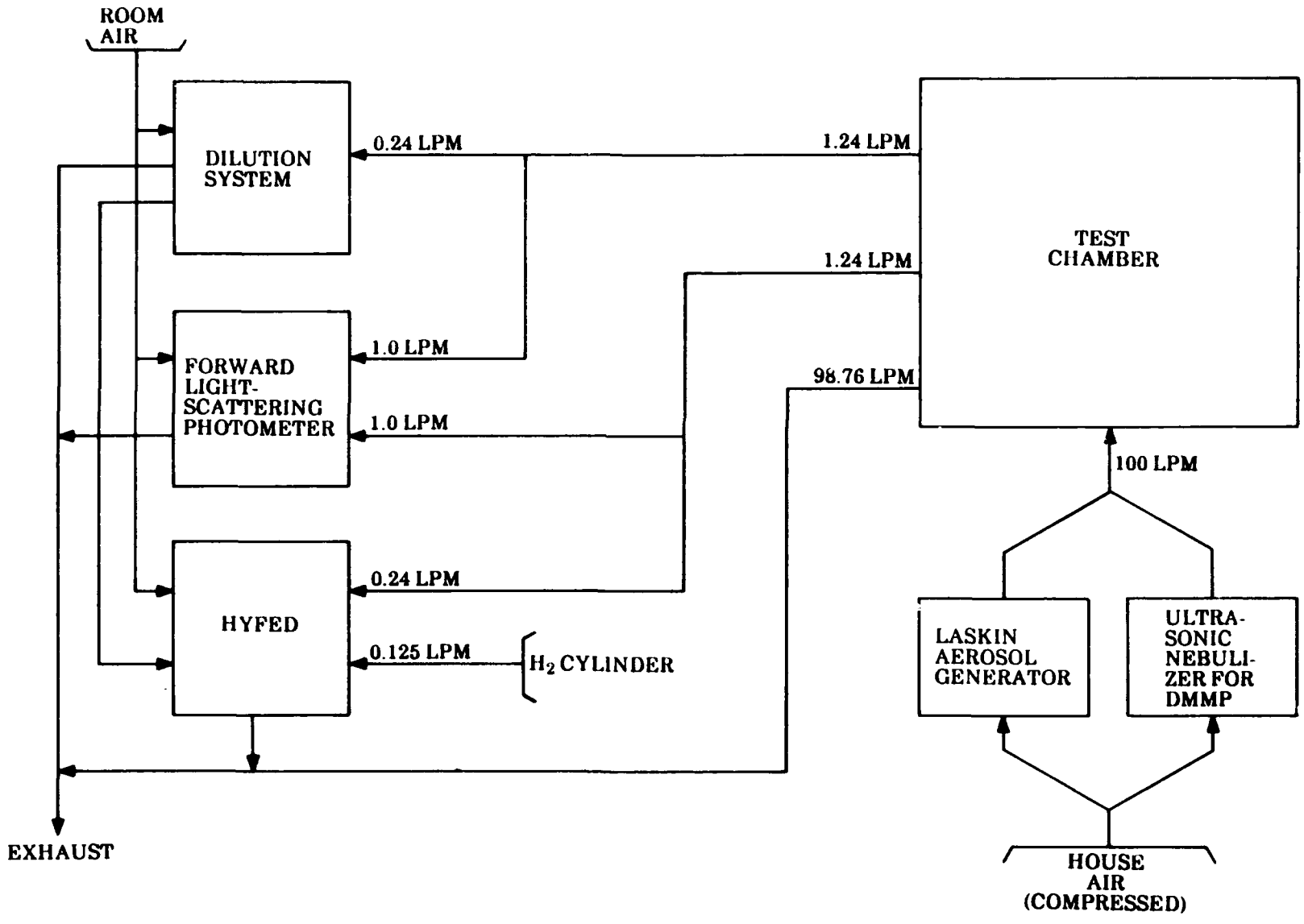


Figure 1. Apparatus Schematic for Simultaneous Vapor/Aerosol Measurement.

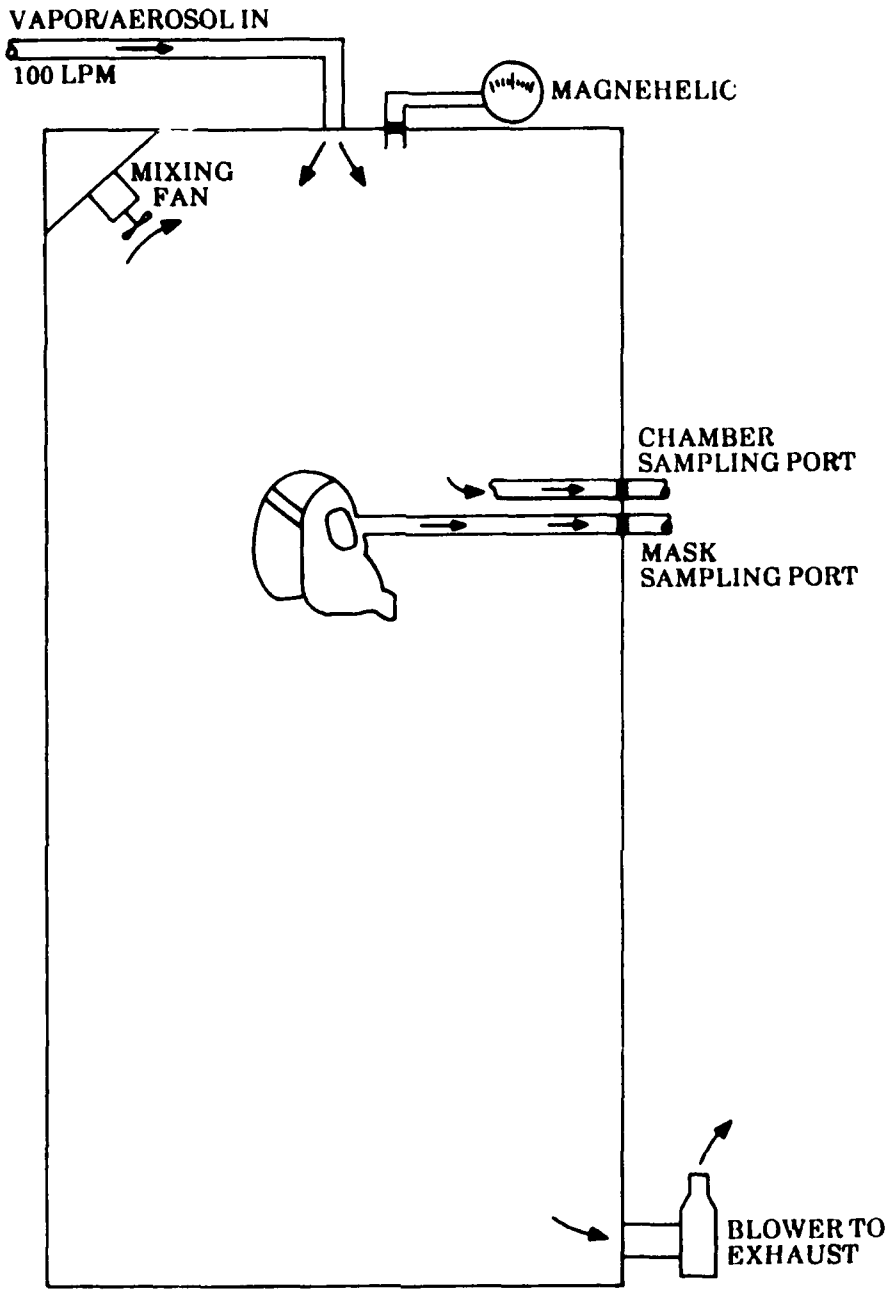


Figure 2. Test Chamber.

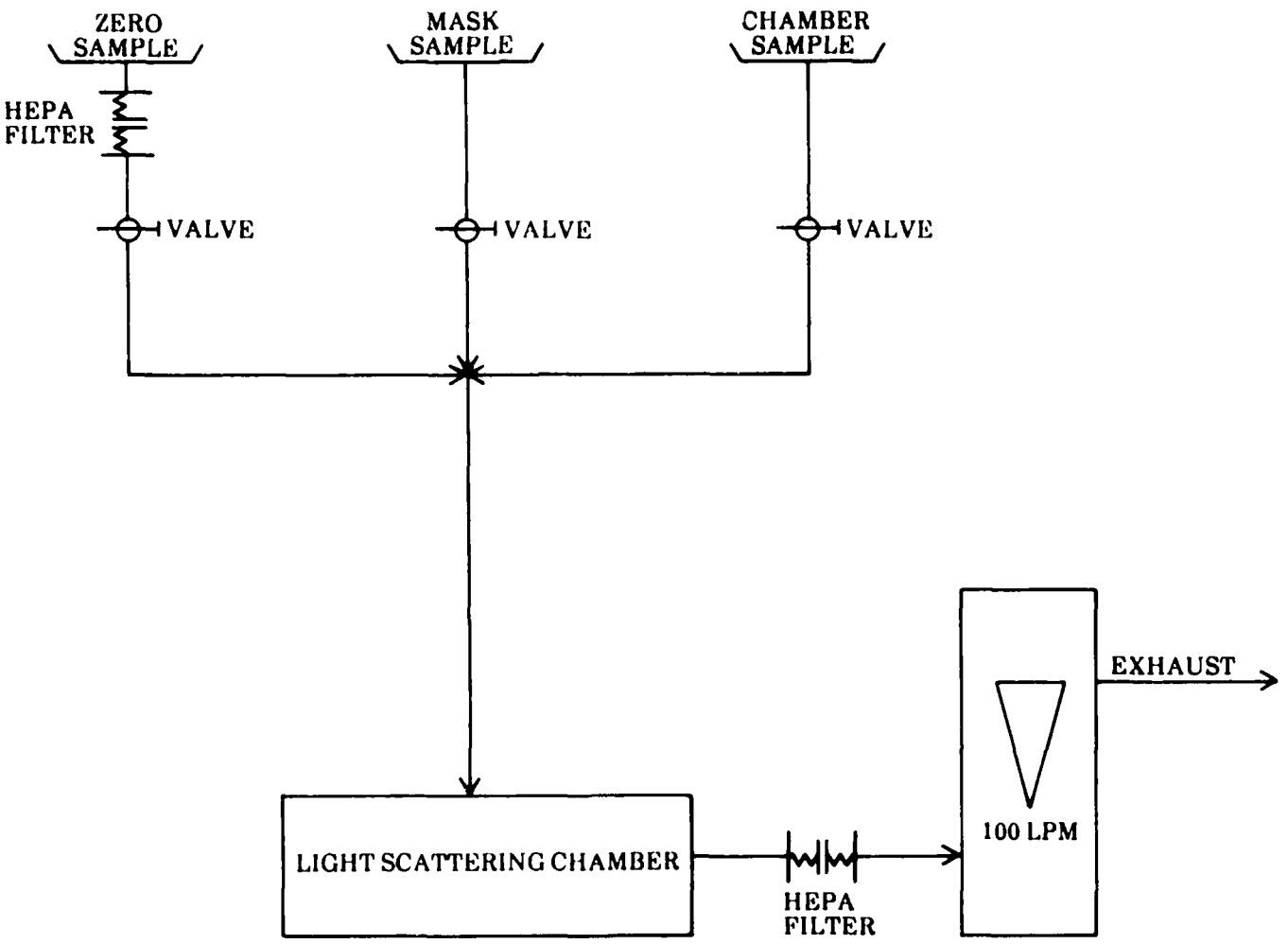


Figure 3. Flow Diagram for Light-Scattering Photometer.

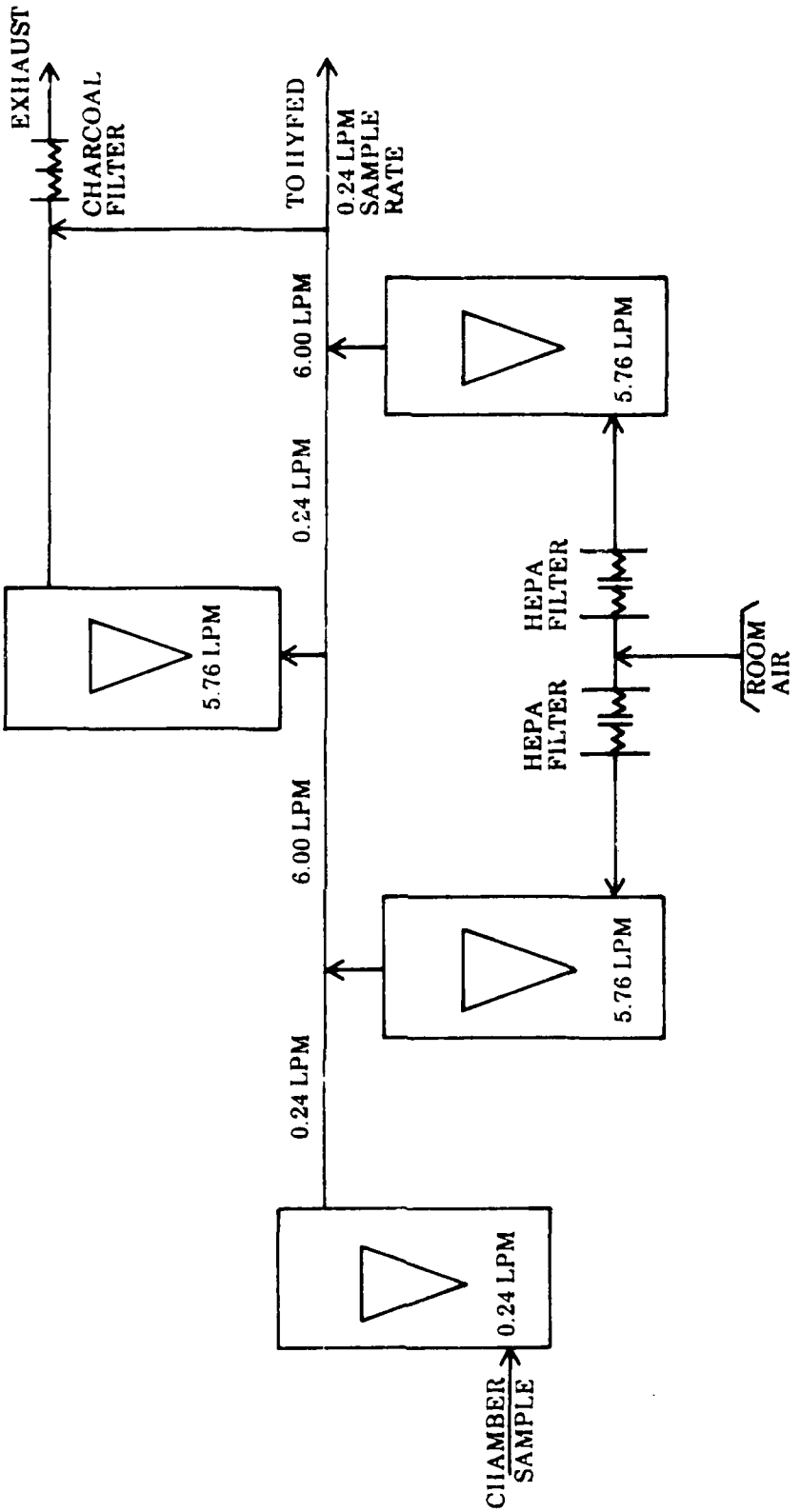


Figure 4. 625: 1 Dilution System.

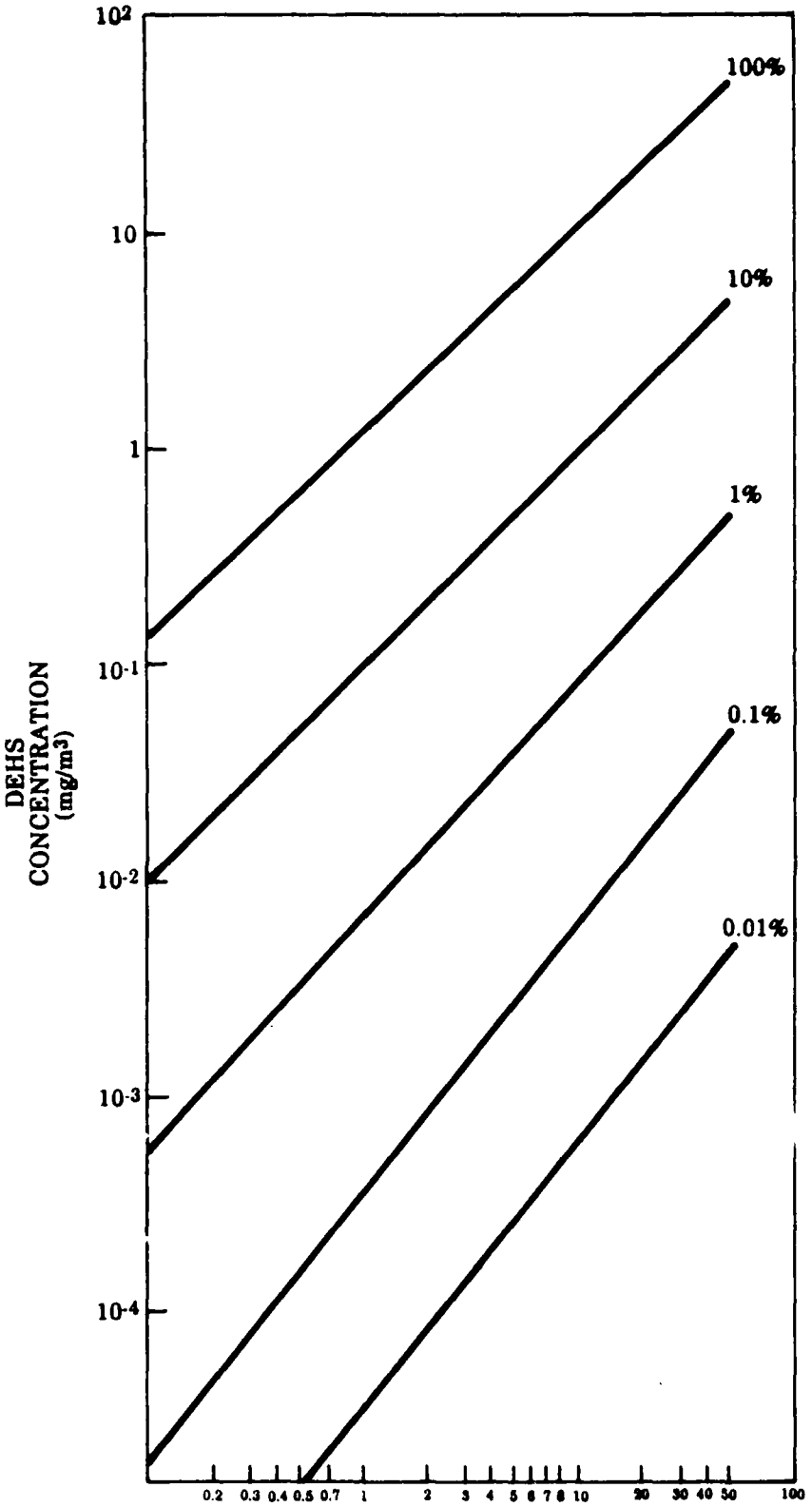


Figure 5. Forward Light-Scattering Photometer Calibration Curves.

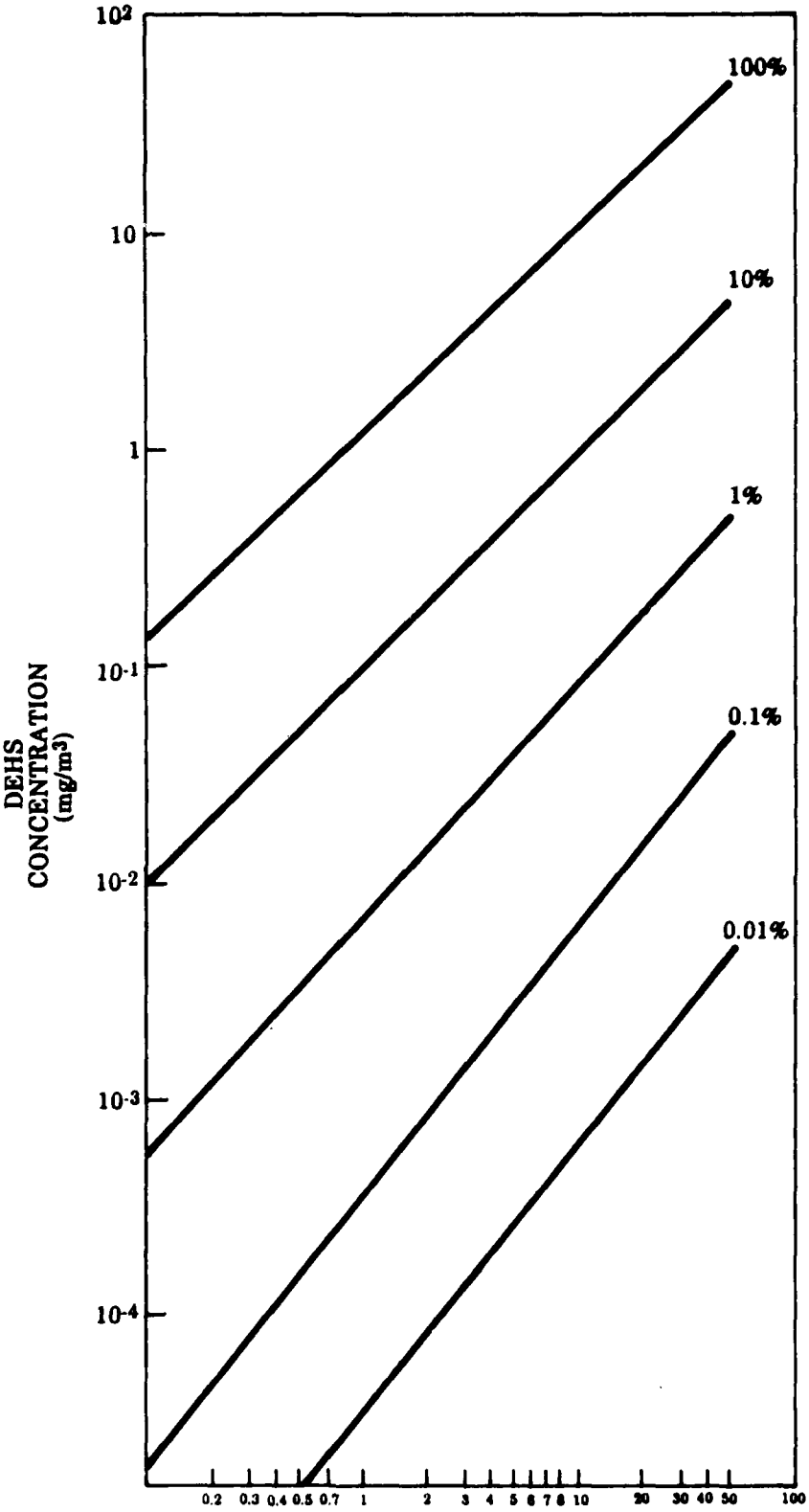


Figure 5. Forward Light-Scattering Photometer Calibration Curves.

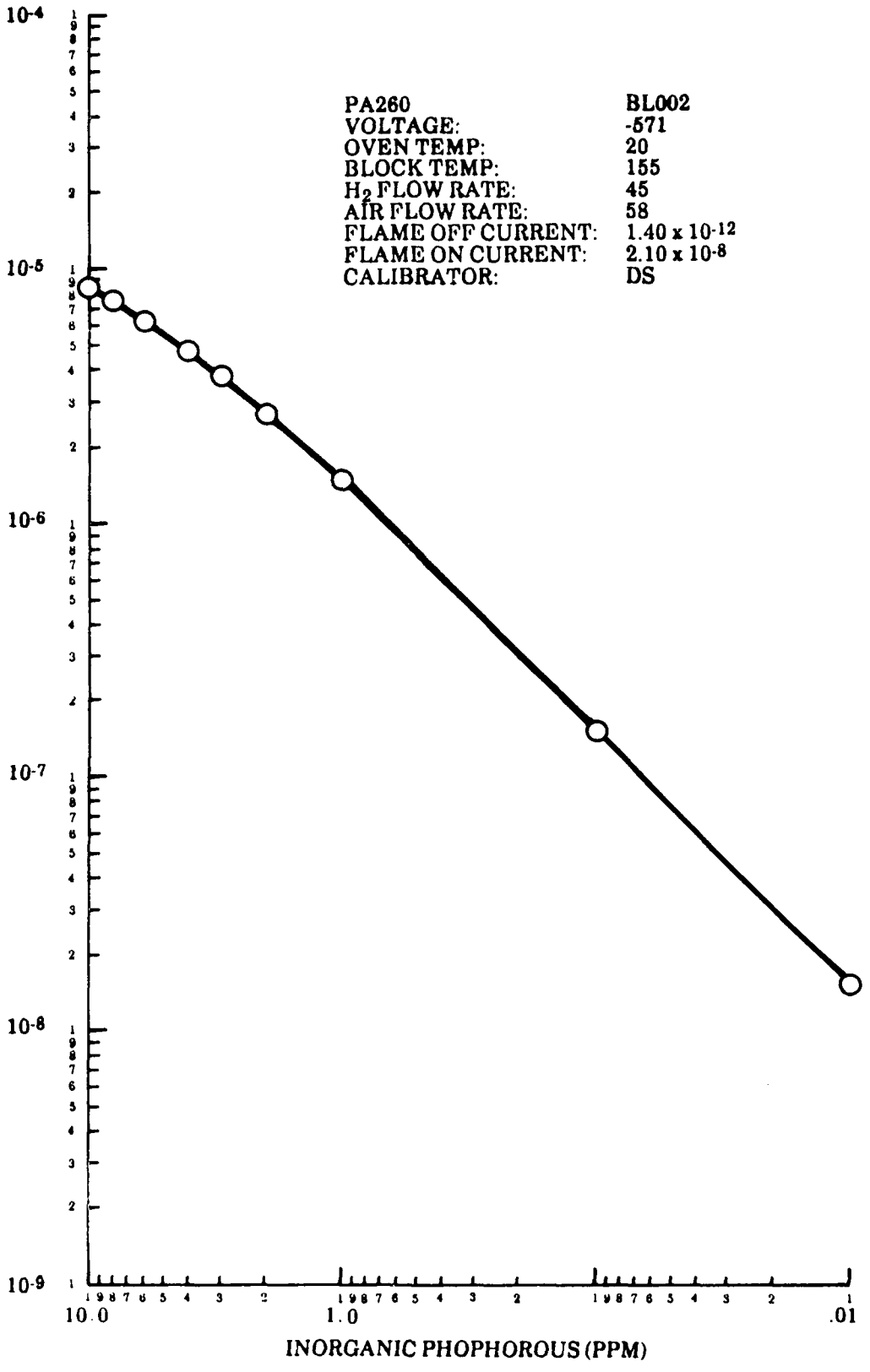


Figure 6. DMMP Calibration.

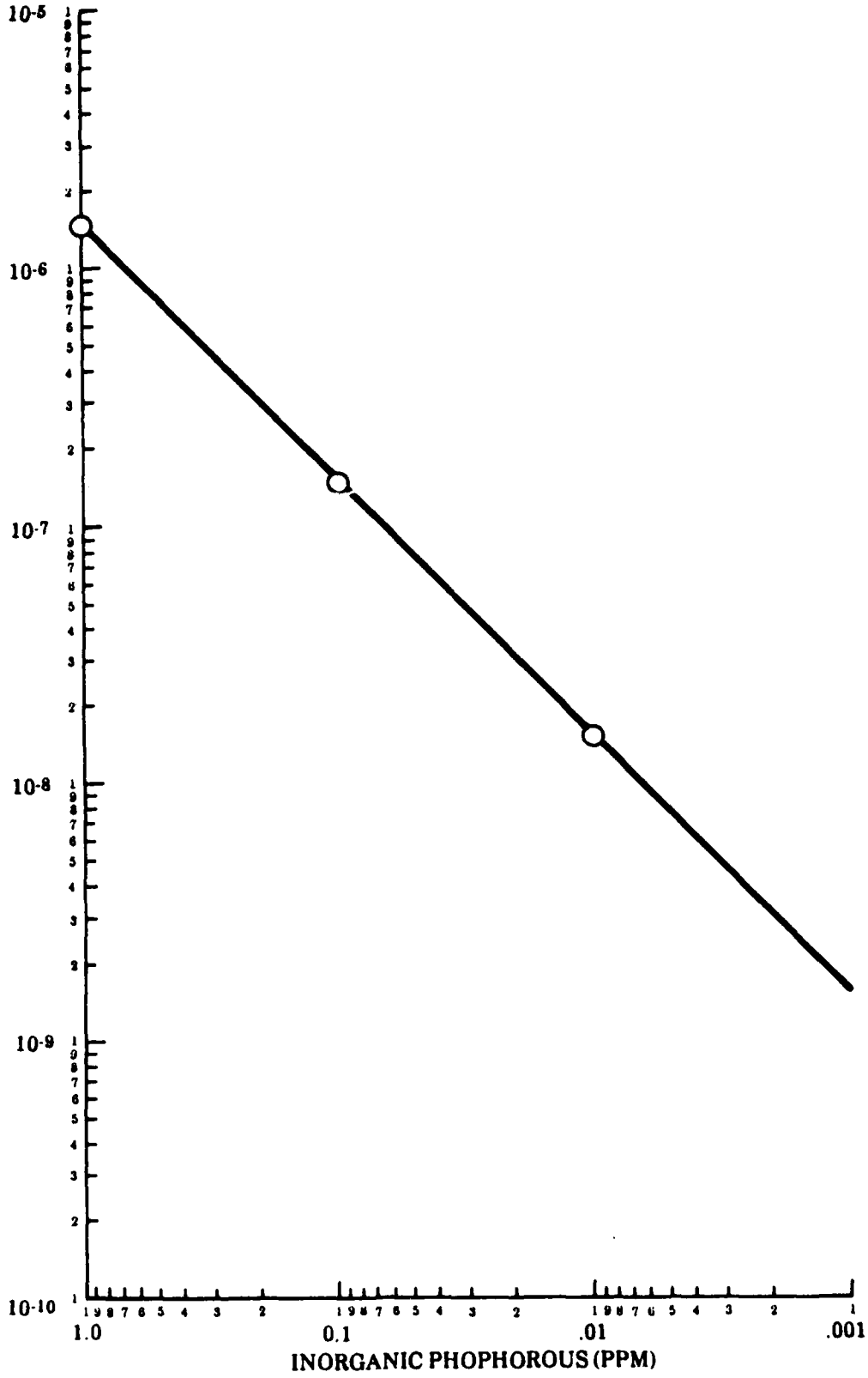


Figure 7. DMMP Calibration.

6. INITIAL TEST RESULTS.

Because of difficulties in establishing a dilution system for DMMP and instrument component failures of the HYFED, it was not possible to carry out actual leakage measurements with the vapor agent. The completion of this phase of the system is the first priority of continuing work.

We did carry out a series of experiments on three subjects with the DEHS aerosol measuring mask leakage on two different days. The results of these studies are shown in Figures 8, 9, and 10. The system for aerosol concentration worked very satisfactorily; we were able to detect within breaths, changes in leakage easily from one head movement or breathing style to another.

We also carried out a study to test interference of DMMP in the photometer measurement of DEHS. To simulate the worst condition, we generated 100 ppm DMMP and introduced it to the photometer at the most sensitive level, producing a signal of about 20%. Based on the expected leakage of the agents, we belive this represents a negligible degree of interference.

We conclude that this system is capable of making the kind of simultaneous leakage measurements that we have proposed. We plan to carry out these measurements as soon as the program can be reactivated.

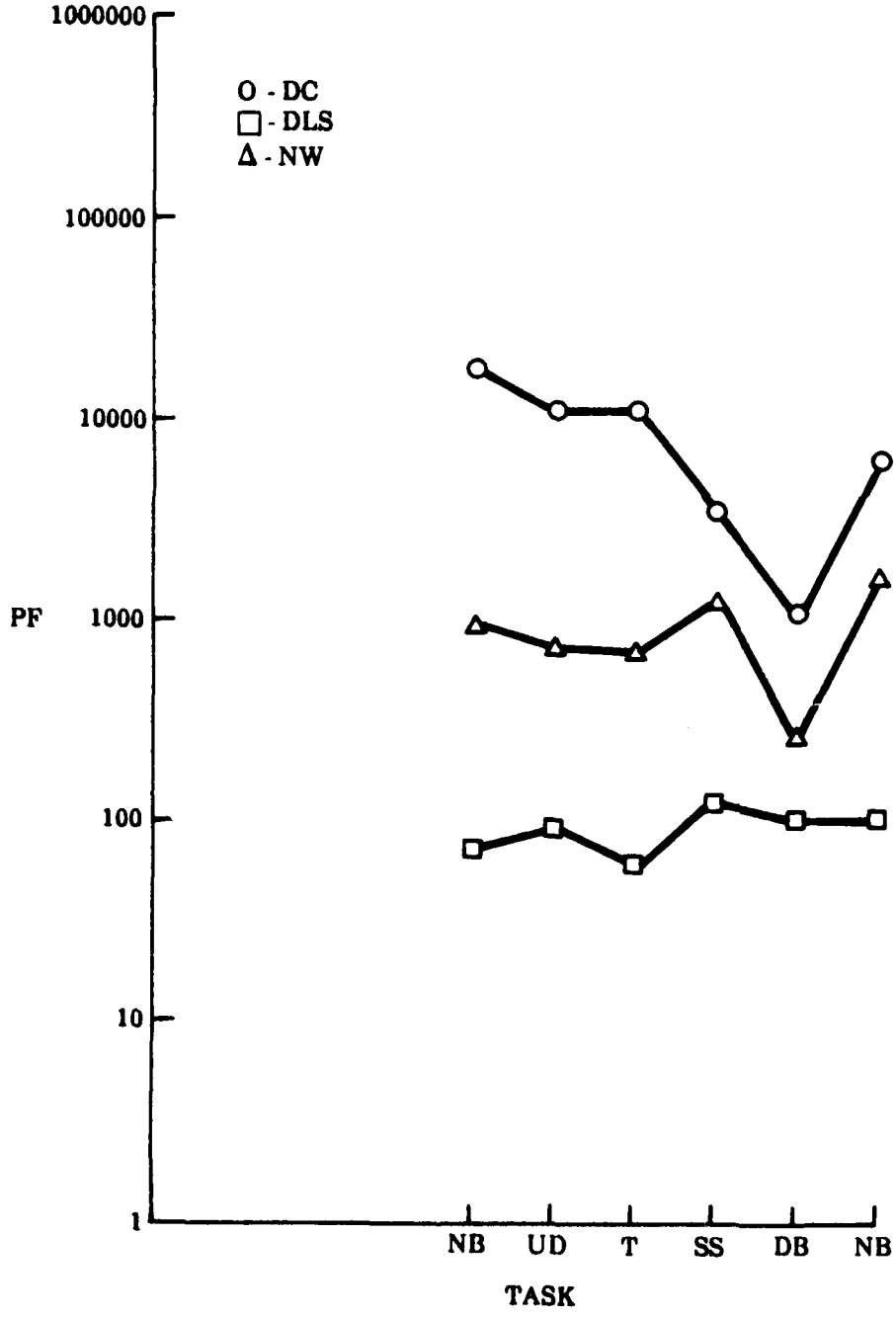


Figure 8. Chamber Aerosol Penetration M17A1 Mask - 3 Subjects, Day 1.

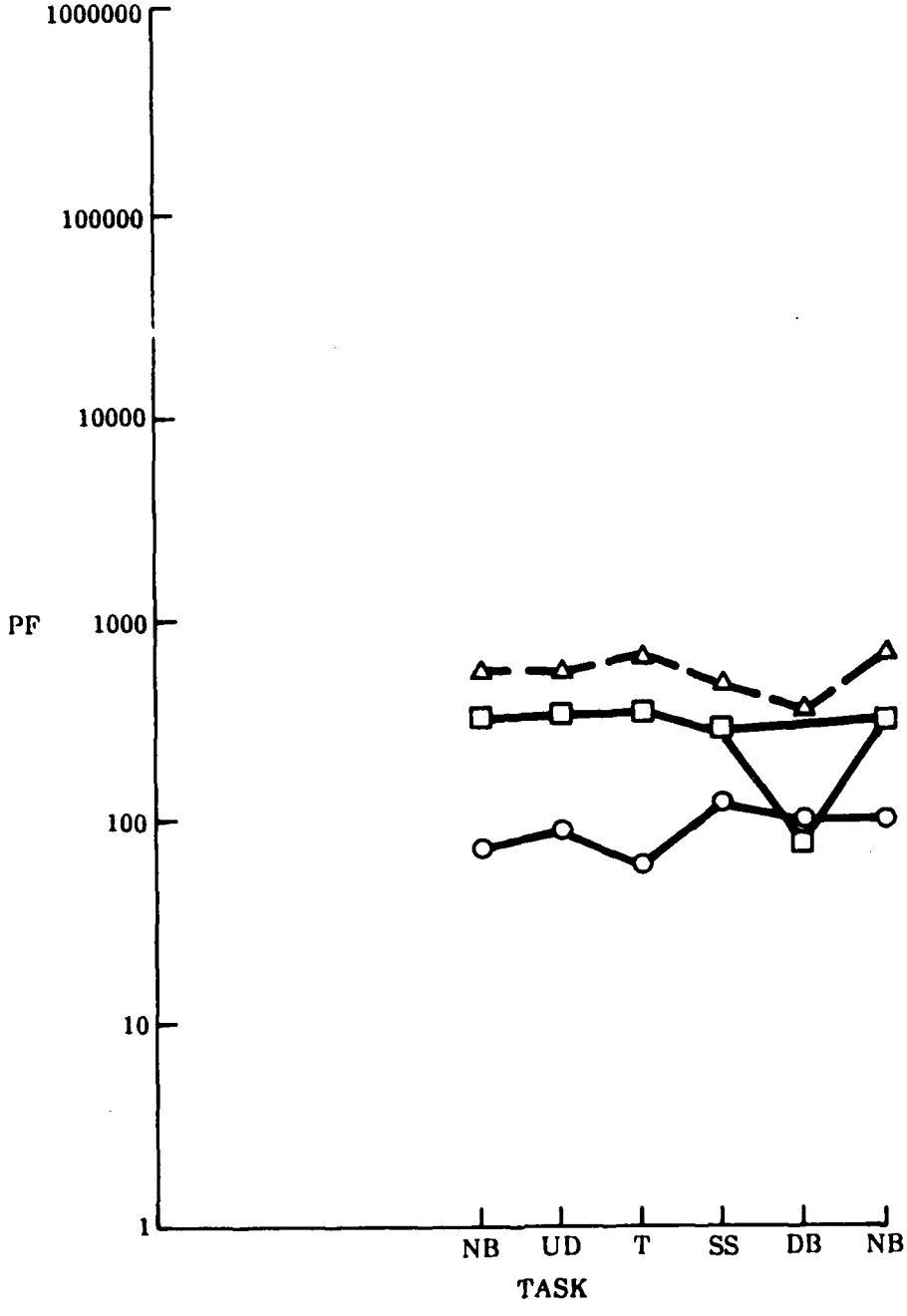


Figure 9. Chamber Aerosol Leakage-M17A1 Mask - Same Subject, Different Days.

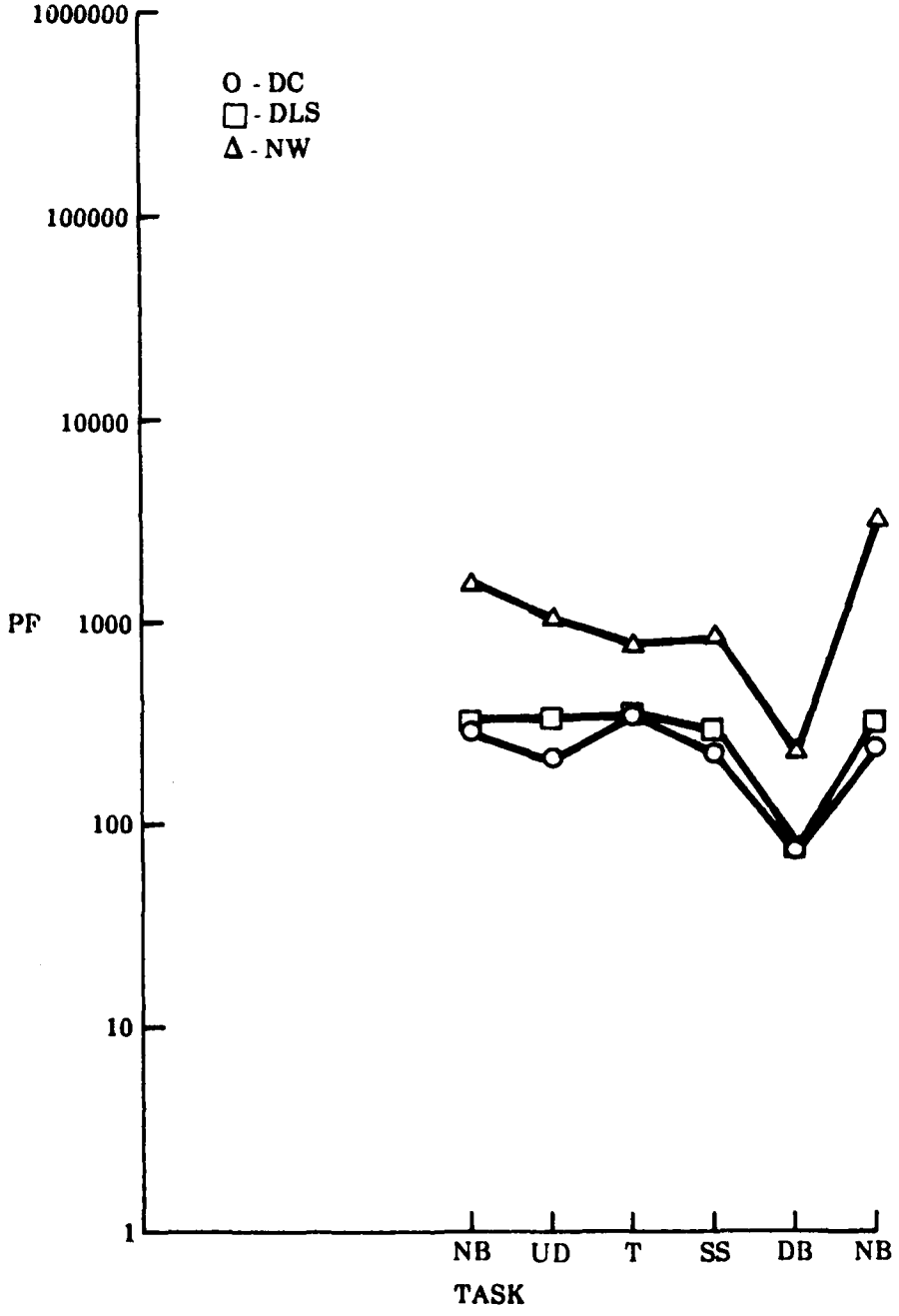


Figure 10. Chamber Aerosol Leakage-M17A1 Mask - 3 Subjects, Day 2.

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APPENDIX H

NEEDED RESEARCH

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QNFT - NEEDED RESEARCH AND SPECIFIC RECOMMENDATIONS

1. INTRODUCTION

One of the major purposes of the Peer Review Meeting held at Johns Hopkins in March 1983 was to identify gaps in the data base of QNFT methodology and mask leakage and suggest needed research. Many suggestions were made and these are centered in the report of that meeting. The section that follows draws on this information, but contains our own assessment of the research priorities and approaches that ought to be taken in advancing respiratory protection science and engineering.

2. GAPS IN THE DATA BASE.

A review of literature concerning mask leakage indicates considerable engineering effort over a period of 100 yr but a notable lack of scientific foundation. Up to the present, the requirements for respirator performance have not been well defined, but with improved techniques and more research workers becoming interested in the use of respirators, the lack of basic information hampers developments that could greatly improve the performance of these devices. We shall first consider knowledge gaps in mask leakage and their needs for QNFT methodology.

A primary issue that requires study is leakage rate of particles, vapors, or gases and its relationship to agent chemical and physical properties. For gases and vapors, this includes molecular weight, diffusion properties, water solubility, chemical reactivity, surface adsorption, and surface interaction with other substances. For aerosols, this includes particle size, particle concentration, electric charge, chemical reactivity, and hygroscopicity. Studies of leakage performed to date have employed simple agents. The effect of these other parameters on leakage needs to be known if leakage testing is to be a reliable predictor of actual performance.

Another significant gap in data is the issue of gas and aerosol mixing within the mask cavity. This factor has many implications in terms of the fate of materials entering the mask cavity at different locations. Very little is known about how the shape and size of the mask cavity and the location of filters, valve, and oronasal cup influence the pattern of inspiratory and expiratory flow. No scientific studies have been carried out to investigate the nature of flow and mixing within a

respirator cavity. However, such studies are needed to predict exposure to leaked substance and to aid in future design.

The specific location of leaks and effects of movement on such leaks are another area for the development of research techniques. At present, all leakage methods measure overall leaks and no QNFT methods can be used to identify the specific location and associated degree of leakage. Such techniques of quantitative leak location need to be developed so that design changes intended to improve seal can be critically tested and major sites of leakage identified.

With emphasis on high level of protection against agents, it is important to reexamine the operation of valves, particularly with respect to their operation under field conditions and with rapid head movement. The criteria of positive seal and low pressure drop, that has guided valve design in the past, needs to be looked at critically to see if new designs are needed.

In the area of specific QNFT methodology, perhaps the most important need is the development of methods that would enable mask leakage to be measured at issue and in field use. Studies carried out by investigators report differences between laboratory leakage and field leakage values. This questions the fundamental assumption that a properly conducted QNFT is a valid predictor of field operation. The reasons for the differences are not known and research is needed to elucidate why such differences are observed and if these observations are true for military respirators.

The need for field measurements of mask leakage is a strong motivation for the development of non-intrusive fit testing methods. This has been discussed in detail in Appendix F. No reliable method of this type exists at present and research is required to provide for such a technique.

The effect of sampling from the mask cavity for concentration measurement is not known; nor is the effect of flow rate on leakage. If techniques are developed not requiring sampling, it would be useful to compare measurement with the two methods. The effect of lung removal of particles or vapors is also an important issue that has received little past attention. It has been stated that NaCl aerosols are 80% removed while oil aerosols are probably only 20% deposited in the respiratory tract. A study to evaluate the influence of this factor would aid in the choice of QNFT methods.

As the need to measure higher degrees of protection is realized, it is important to determine the calibration of both NaCl and oil aerosol at very low concentration, using an "absolute" method that does not make assumptions about dilution or linearity of instrument responses. Present methods of dilution are unreliable about 1000 X and need to be checked with methods independent of the above assumptions and sources of error.

3. SPECIFIC RECOMMENDATIONS FOR RESEARCH

Studies to investigate the effect of particle size and electric charge on aerosol leakage need to be undertaken. This should be done initially on a mannequin or other system that can be carefully "microleaked" to a specific degree. With data from these studies, further studies on a small number of human subjects should be performed to confirm the findings 'in vivo'. These studies require 2+ yr to obtain adequate information.

Studies of leakage of gases with markedly different solubility and adsorption properties should be performed. Comparative measurements should be carried out. Particular attention should be given to skin absorption in human studies. Similar effort to the aerosol studies are required.

Techniques to measure air movement within the mask cavity must be developed and applied to studies of air mixing. Visualization using smoke, or dye in liquid flow analogs may be employed. Effects of the oronasal cup need to be known in view of the observation that rebreathed CO_2 is higner with such configurations. This is a 2-yr effort to obtain some information to assist in new cavity and flow design.

A study should be carried out to develop methods of localizing leaks during testing. Several ideas have been proposed for this study including local aerosol delivery and dividing the facepiece seal into sectors by plastic film boundaries. Six months are needed to develop techniques and 1 yr is needed to study the locale of leaks.

The field performance of respirators should be studied. This task requires significant planning to develop a method so that comparison between laboratory and field can be made. This is a large effort, but critical to the assurance of proper field performance. It should require at least a 2-yr effort.

Calibrations of QNFT methods at low agent concentration should be made. This is important if confidence in high values of protection factor are required. This effort is achievable in 1 yr or less.

The dynamics of valve operation should be studied to assist in future valve design. Accelerations that are associated with movement and rapid breathing should be included as a factor. This effort requires about 1 to 1 1/2 yr.

APPENDIX I

LABORATORY INSTRUMENTATION FOR AEROSOL RESEARCH

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AEROSOL SCIENCE AND TECHNOLOGY LABORATORY RESOURCE REQUIREMENTS

1. INTRODUCTION

This section outlines principal instrument and resource requirements for a modern aerosol laboratory for respirator research and development. Types of research to be performed include studies on behavior of particles (motion) as controlled by fluid motion and interactions with other particles or gases, boundaries, and obstacles in the flow (e.g., filter fibers). Principal parameters under investigation include particle concentration (mass, number, or area per unit volume of suspending gas); particle sizes; material composition and chemical species; and the size-spectral distribution of these and other properties (e.g., electrostatic charge) or characteristics (e.g., deposition and accumulation).

The systems to be developed for aerosol research may be divided into areas of:

- Generation
- Sampling
- Analysis
- Flow Systems and Chambers
- Personnel Requirements
- Facility and Support Requirements

2. GENERATION

2.1 Purpose.

The purpose of aerosol generations systems is to provide a continuous and reproducible suspension of aerosol particles with defined physical and chemical composition, characteristics, and properties. Principal generator performance characteristics include particle size or range of sizes produced, type of materials, and concentration range attainable. Generators are divided into 3 broad categories based on properties produced: monodisperse, polydisperse, or simulant.

2.2 Monodisperse Aerosol Generators.

Typical devices: (L = liquid particle; S = solid or dried residue).

- L LaMer-Sinclair (Vaporization-condensation) (Thermal DOP) Generator.

  - Commercial Sources: not commercially available
  - Approx. Cost: easily built with standard apparatus ($10,000 est.)

- L Rappaport-Weinstock (Devir) (V-C) Generator

  - Commercial Sources: TSI
  - Approx. Cost:

- L, S Spinning Disc (Walton & Prewett/Porton) Generator

  - Commercial Sources: BGI, TSI
  - Approx. Cost:

- L, S Vibrating Orifice:

  - Commercial Sources: TSI
  - Approx. Cost:

- L or S Nebulizers with monodisperse PS latex suspensions

  - Commercial sources: DeVilbiss, pneumatic or ultrasonic and several others, Dautrebande, Collison
  - Approx. Cost: ultrasonic ($1,000 est.); pneum. (< 100)

2.3 Polydisperse Aerosol Generators.

Typical Devices: (L = liquid particle; S = solid or dried residue).

- L or S Nebulizers for liquid particles or dry residues

- S Powder Feeder plus Air Jet Ejector Redispersion

- Wright Dust Feeder -
- NBS - BGI
- Turntable Feeder - Wiedeman
- Fluidized Bed - TSI

  - Commercial Sources: various, TSI, BGI, etc.
  - Approx. Cost: $1,000 or less (est)

2.4 Simulant Generators.

Any of above

Explosive dissemination devices

Combustion fume (arc, flame)

Also see chapters in Handbook on Aerosols and Air Sampling Instruments Manual.

3. SAMPLING

3.1 Purpose.

The purpose of aerosol sampling is to extract a representative portion or aliquot of the aerosol system and to collect the portions of interest (particles or gases). "Representative" implies unbiased in properties, characteristics, or composition of the substances under investigation, and usually refers to particle size and concentration. Some systems are amenable to in situ sampling and analysis (e.g., light scatter, obscuration or absorption, optical range, back scatter, other EMR interaction, etc.). Sampling devices may involve collection and subsequent analysis of a property within the same device. See Air Sampling Instruments Manual (ASIM) (1983) for latest products and vendors.

3.2 Collectors.

3.2.1 Particle Collectors.

- Mechanical Collectors
  - Settling chambers
    - Tymbrell

Hexhlet
Cotton Dust Elutriator
Commercial Source: Cassella
Approx. Cost: (< $100)
Cyclones
10 mm Nylon
1-3 in diam. steel, etc.
Commercial Sources: several (ASIM)
Approx. Cost low (< $100)
Series and parallel arrangements, e.g. cascade cyclones
Sources: Flow Gen.
Approx. Cost $1,000 (est.)
Impingers
Standard Greenburg Smith
Midget
Sources: Several (ASIM)
Approx. cost low (< $100)
Impactors
[See Table 1 (ASIM)]
Commercial Sources: See table
Approx. Cost: $1,000 (est.)
Diffusion Batteries
Rect. or round channels

- Scrubbers

- Electrostatic Precipitators

Single cyl: wire in tube
Commercial Source, MSA, Del Electronics
Approx. Cost $1,000 (est.)
Parallel Plate (ASIM)
Commercial Source: TSI
Approx. Cost $1,000

- Filters

Several types; fibrous, membrane, pore, granular
cost low

All above devices require sampling pumps and flowmeters, etc., see ASIM for typical and vendors,

Table 1. Principal Design Features of Cascade Impactors Used for Gas Stream Sampling (8/82).

No	Manufacturer and Model	Jet Design	Design Flow Rate cfm	(lpm)	No. Stages	Precollector Type & $AED_{50}\mu m$	AED_{50}, μm; at Design Flow Rate at Stage No. Indicated 1	2	3	4	5	6	7	8	9	Backup Filter
1	Andersen Mark III	Multi-hole (400?)	0.5	(14)	7	Impact, 12.2	8.4	5.7	3.9	2.5	1.2	0.77	0.52			Flat f g
2	Andersen High Capacity	2 Impact chambers	0.5	(14)	3	—	10.8	5.8	1.5	(cyclone)						Thimble
3	Battelle-Delvon DCI-5	Single round		(1)	5	—	4.0	2.0	1.0	0.5	0.25					Flat f g
4	Battelle-Delvon DCI-6	Single round		(12.5)	6	—	16.0	8.0	4.0	2.1	1.0	0.5				Flat f g
5	Brink Monsanto SORI-Zoltek	Single round (after Ranz & Wong, Cup)	0.1	(2.8)	7	Cyclone, 17	10.0	6.2	3.0	1.6	1.1	0.55	0.32			Flat f g
6	Casella-(May)	Single Rectangular		(17)	4	-	12.3	3.8	2.0	1.1						Flat f g
7	Flow Sensor Hill	Multi-hole (400?)	0.5	(14)	8	Cyclone 11	6.6	4.4	2.9	2.2	1.4	0.88	0.55			Flat f g
8	Gelman-	Mentioned in Contents of this volume														
9	Hering-Friedlander CII	Single rd. lo pr (DCI 50 mod)		(1)	8		4.0	2.0	1.0	0.5	0.26	0.12	0.075	0.050		Flat f g
10	Mercer Aries	Single round		(0.8)	7	-	5.1	3.3	2.4	1.8	1.2	0.81	0.37			Flat membrane
11	Meteorology Rsch Inc-MRI	Multi-hole (24?)	0.5	(14)	7	Impact, 30(?)	20.0	7.0	3.5	2.5	1.5	0.7	0.3			Flat f g
12	Sierra-226	Radial slots	0.75		5	-?-, 10	8.6	3.9	2.4	1.2	0.61					Flat f g
13	Sierra-ERC Tag	Parallel slits	0.5	(14)	9	Impact, 30	12.3	8.3	5.6	3.8	2.6	1.8	1.0	0.7	0.6	Flat f g
14	U Wash-Mk III-Pilat PSC	Multi-hole (variable, i.e. 12,90,110 etc.)	1.0		7	Impact, 30(?)	22.0	9.5	3.6	2.8	1.0	0.51	0.27			Flat f g
15	A.P.I.-M-I	Not available commercially (1977)		(20)	7		13.0	9.7	6.0	2.2	1.1	0.58	0.39			

3.2.2 Gas and Vapor Collectors.

- Absorption (Scrubbers) (i.e., water, TEA, etc.) e.g., impingers (see above)

  - Bead columns, helixes, plate, packed, etc.
  - Several sources, low cost.

- Adsorption

  - Charcoal, silica gel, zeolites, etc.
  - Several sources, low cost

- Combustion

  - Direct flame, catalytic
  - Several sources, low to medium cost.

- Chemisorption

  - Specific for gas (e.g., CaO for CO_2)

- Condensation

  - For condensible vapors (e.g., water)

All above devices require sampling pumps, flowmeters, and may require other utilities, reagents, or condensibles.

3.3 Aerosol Analyzers (May Sample and/or Analyze).

- Light Scatter Photometers and Size Analyzers

  - Royco - several models, approx. cost, $10,000
  - HIAC
  - Others

- Laser Light Scatter

  - Spectrex
  - PM Systems Inc.
  - Active Cavity (Laser) Aerosol Spectrometer
  - Approx. Cost ($16,000)
  - (Knollenberg)

- Electrical Aerosol Analyzer

  - Commercial Source, TSI, several models
    Approx. Cost, > $10,000

- Vibrating Quartz Crystal Microbalance Cascade Impactor

  - Commercial Source: QCM, Berkley Controls
  - Aprox. Cost

- Aerosol Centrifuges (also possible with Quartz Crystal Sensor) Stoeber Spiral Duct (Sorvall) Centrifuge

- Beta Gage Mass Monitors

  - Commercial Sources GCA Technology Div.
  - Approx. Cost: $10,000 or less

See Table 2, attached (ASIM).

4. ANALYSIS

4.1 Purpose.

Analysis of an aerosol system may be directed to measurements of particle size, number, area, total mass, composition, morphology, charge, and other characteristics or properties (e.g., shape, density, etc.). Broadly, one is concerned with measurement of physical or chemical parameters related to effects produced by the individual particles or to the total cloud and its motion, deposition, etc.

4.2 Physical Analysis.

Physical analysis generally involves measurement of particle size spectra and the quantity of material in each component of the size distribution. Other properties of interest include shape, density, and surface phenomena. Instrumentation for physical analysis include standard laboratory apparatus such as SEM/TEM/ microscopy, charges, or voltage, etc.

4.3 Chemical Analysis.

Chemical composition is usually determined by conventional analytical laboratory instruments such as atomic

Table 2. Direct Reading Instruments for Analyzing Airborne Particles.

absorption, gas-chromatography, XRF, etc. from collected samples of the aerosol particulate material. Services of such a laboratory are required.

5. FLOW SYSTEMS AND CHAMBERS

Aerosol research will require one or more suitable chambers for the generation of static clouds of particles for use in calibration, test, or exposure. Typical chambers may range in size from 20-40 L, up to several hundred or a thousand cubic meters (e.g., room size). Larger chambers are equipped with access locks, viewing windows, instrument access ports, lines, etc. Small to medium chambers are typically glass (carboys) or glass-lined tanks. For dissemination research, high-pressure designs may be necessary.

Flow systems have advantages and may be used for certain types of aerosol research. Aerosol tunnels are essentially wind tunnels with a defined flow field in the test section, plus the addition (upstream) of suitable particle generation and administration apparatus. Tunnel sizes may be 1 in and up to several ft in diameter at the test section. Both chambers and tunnels represent a long-term capital equipment investment.

6. PERSONNEL REQUIREMENTS

A senior aerosol scientist/engineer is required for overall planning and management of test programs. Qualifications include education (Ph.D), experience (10-20 yr productive research), and national stature (e.g., of the stature of Henry Green of Porton). An administrative staff is required to oversee procurements, budgets, library, and facilities. Specific technical staff will include aerosol/environmental engineers, physicists, chemists, and depending upon the nature of work, aerosol toxicologists.

7. FACILITY AND SUPPORT REQUIREMENTS

Other resources include experimental mechanical shop with modeling and molding capabilities, an electronics shop, a library, suitable research modules, and offices adjacent. Access to main frame computer facilities and mini-computers to process data on-site are essential.